HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
FEBRUARY 26, 2014
APPLICATION SUMMARY

NAME OF PROJECT:	Karing Hearts Cardiology, PLLC
PROJECT NUMBER:	CN1311-046
ADDRESS:	701 N. State of Franklin Road, Suite 2 Johnson City (Washington County), TN 36404
LEGAL OWNER:	Karing Hearts Cardiology 701 N. State of Franklin Road, Suite 2 Johnson City (Washington County), TN 36404
OPERATING ENTITY:	Not Applicable
CONTACT PERSON:	John Wellborn (615) 665-2022
DATE FILED:	November 15, 2013
PROJECT COST:	$391,585.00
FINANCING:	Commercial Loan
PURPOSE FOR FILING:	Initiation of positron emission tomography (PET) services and acquisition of PET equipment

DESCRIPTION:

Karing Hearts Cardiology, PLLC, is seeking approval to initiate cardiac PET services and to acquire cardiac PET equipment by lease at its practice office located at 701 State of Franklin Road, Suite 2, Johnson City (Washington County), TN 37064. The PET equipment will be acquired from Molecular Imaging Alliance which has a recently approved unimplemented CON approved at the July 23, 2013 Agency meeting for the relocation of its Outpatient Diagnostic Center (ODC) and positron emission tomography (PET) services from 830 Suncrest Drive, Suite 1, Gray (Washington County), TN to the "701 Building", State of Franklin Road, Suite 1, Johnson City (Washington County), TN.

Karing Hearts Cardiology, PLLC currently leases Suites 1, 2 and 3 of the "701 building" and now has integrated all three suites into a single practice office. Suite 1, which was to be leased to Molecular Imaging, no longer exists as a separate space. Karing Hearts Cardiology, PLLC now uses "Suite 2" as the address for its entire 3-suite office.

A certificate of need is required since there will be a change of PET equipment ownership and, if approved, the proposed PET service will be changing from being provided in an Outpatient Diagnostic Center (ODC) to a physician practice.

SPECIFIC CRITERIA AND STANDARDS REVIEW:

POSITRON EMISSION TOMOGRAPHY SERVICES

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

   For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

   The applicant projects the cardiac PET will perform 678 PET procedures in the first year of operation (2015) increasing to 745 in the second year (2016). Since the PET will be restricted to cardiac procedures, the applicant states the unit will likely not ever perform the minimum recommended procedures. The proposed PET utilization was projected from trending past increases in demand for the PET service within Karing Hearts Cardiology.

   It appears that this criterion has not been met.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed

service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

The applicant projects 85.3% of patients will come from the three county service area. The applicant provides a table on page 20 of the application of the distance and drive time from the proposed PET location (Johnson City, TN) to 3 major cities within the service area. The driving distance ranges from .8 miles to Johnson City (Washington County), TN to 18.2 miles to Elizabethton (Carter County), TN.

It appears that this criterion has been met.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

There are no other cardiac PET providers in the primary service area. Wellmont Cardiology in adjacent Sullivan County has a cardiac PET system; however the applicant points out the further distance to Sullivan County, that it is limited to the patients of Wellmont Cardiology and the unit is expected to be at full capacity within three years. It should be noted that the applicant did not state that a sharing arrangement was investigated. It should also be pointed out that both cardiac PET units have historically not met the State Health Plan's PET utilization standard.

It appears that this criterion has not been met.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

The proposed PET is for cardiac PET procedures.

This criterion does not apply.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

In 2012 the overall PET units in the service area operated at a volume that was at 46.4% of the PET minimum utilization standard. The applicant is projecting 678 PET procedures in Year One and 745 PET procedures in Year Two.

It appears that this criterion has not been met.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.

   a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

      A FDA approval letter was included in the attachments to the application.

      It appears that this criterion has been met.

   b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

      A letter from an architectural firm indicating compliance with current building codes and healthcare guidelines applicable to the project are included in the attachments to the application.

      It appears that this criterion has been met.

   c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

The applicant provided a copy of the Cardiac PET Clinic Emergency protocols in the attachments to the application.

It appears that this criterion has been met.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

Protocols to assure medical appropriateness and medical necessity were included in the attachments to the application.

It appears that this criterion has been met.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

Dr. Jeffrey Schoondyke, a board certified cardiologist, will be the Medical Director of the proposed cardiac PET service. Karing Hearts Cardiology currently holds a Tennessee radioactive material license which expires August 31, 2023.

It appears that this criterion has been met.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

If approved, the applicant will seek a transfer agreement with Johnson City Medical Center (JCMC). Dr. Jeffrey Schoondyke is an active member of the medical staff at JCMC.

It appears that this application intends to meet these criteria.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

   The applicant states it will comply with all requests from the HSDA for timely data.

   It appears that the applicant intends to meet these criteria.

8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

   a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

      The applicant provides documentation from the U.S. Health Resources and Services Administration that designates the following medically underserved areas: Carter County, Unicoi County, and an MUA designated area of Bethesda Division Service Area within Washington County, TN.

      It appears that this criterion has been met.

   b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

      The applicant did not request special consideration for this standard.

   c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

      The applicant is not a hospital. Criterion not applicable.

   d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

The applicant indicates Karing Hearts Cardiology participates in all area TennCare MCOs and in Medicare.

It appears that this criterion has been met.

Staff Summary

The following information is a summary of the original application and all supplemental responses. Any staff comments or notes, if applicable, will be in bold italics.

History of the proposed PET Equipment and Service

The following section will provide a history of the PET equipment associated with the proposed project. The timeline begins in 2007 and will include events leading up to the filing of this proposed application:

- April 25, 2007- LifeScan Tennessee, LLC, received approval to establish an ODC and initiate PET services (CN0701-010A) with one PET system in Gray (Washington County), TN. The LLC's sole owner was Soteria Imaging, LLC. (LifeScan Tennessee, LLC currently is doing business as Molecular Imaging Alliance)

- April 2008- LifeScan Tennessee, LLC acquired a second PET system at a cost of $150,000. The second PET system did not require CON approval since it was under the $2,000,000 medical equipment threshold requirement.

- December 23, 2010- Soteria Imaging, the owner of LifeScan Tennessee, LLC dba Molecular Imaging Associates, forms LifeScan Leasing of Tennessee to own and lease the two PET units.

- During 2012, Soteria Imaging made the decision to cease PET services and dispose of their holdings. Karing Hearts' Vice-President, Robert Gregory purchases 100% of the ODC.

- Currently, Robert Gregory is the owner of Molecular Imaging ODC, is vice-president and manager of the applicant, Karing Hearts Cardiology, and is manager and part-owner of LifeScan Leasing of Tennessee, LLC.

- Currently, there are four individuals that are owners of LifeScan Leasing of Tennessee, LLC (the company that owns the PET equipment): Julie Bentley, Nurse Practitioner 28%, Jeffrey Schoondyke, MD 28%, Bruce Boggs, MD 28% and Robert Gregory 28%.

- During the year 2013, LifeScan Leasing of Tennessee, LLC sold the second PET to Wellmont Cardiology. Wellmont Cardiology was approved by the Agency in July 2013 (CN1304-013A) to acquire and relocate the PET from Gray (Washington County) to Kingsport (Sullivan County), approximately 10 miles.

- In the same July 2013 Agency meeting, LifeScan Tennessee, LLC dba Molecular Imaging Alliance was approved (CN1304-014A) to move its Molecular Imaging ODC with the remaining original PET unit approved in 2007, from Gray (Washington County) to Johnson City (Washington County). The distance between the two locations is approximately 10 miles. Molecular Imaging Alliance was to lease Suite 1 of the "701 Building" from Karing Hearts Cardiology. This suite was adjacent to the suite occupied by Karing Hearts Cardiology. Karing Hearts Cardiology, PLLC historically has been the largest referral source for Molecular Imaging Alliance's Outpatient Diagnostic Center. This CON remains unimplemented.

- With this application, Karing Hearts Cardiology proposes to acquire PET equipment from LifeScan Leasing of Tennessee, LLC that was approved in the relocation of the Molecular Imaging ODC (CN1304-014). This particular PET unit was the one originally approved during the April 25, 2007 Agency meeting. The owner of Molecular Imaging Alliance, Robert Gregory, wants to exit the ODC business, terminate its lease of the PET unit with LifeScan Leasing LLC, and transfer the leased cardiac PET and equipment to Karing Hearts Cardiology, PLLC. In the supplemental response, the applicant indicates Robert Gregory, after identifying the capital costs of creating and maintaining a licensed ODC, would prefer to allow Karing Hearts Cardiology, PLLC take over the equipment lease and make cardiac PET simply a service of the practice.

- If approved, Molecular Imaging Alliance will surrender its CON to relocate the ODC with cardiac PET (CN1304-014A). A letter dated November 14, 2013 from Rob Gregory, President/Owner of LifeScan Tennessee dba as Molecular Imaging Alliance located in Attachment C, Need—1.A.3.e. confirms Molecular Imaging Alliance's intent to surrender CN1304-014A, if Karing Hearts Cardiology's CON to acquire the PET equipment (CN1311-046) is approved.

- The hours of operation for the PET service are expected to be weekdays 7:00 am to 5:00 pm. If approved, the applicant states the new location can be open for patient service by October 15, 2014.

PET Scanner Equipment

- The PET scanner being relocated is a 2002 GE cardiac PET scanner system that includes the camera, workstation, software, water chiller unit, lead door, in-lab furniture, and miscellaneous items on the lab and control room.
- The PET scanner is valued at approximately $350,000 with an expected useful life of five years.
- The applicant will be leasing the PET scanner system from LifeScan Leasing, LLC at a cost of $12,000 per month.
- A letter dated October 31, 2013 from Precision Nuclear, LLC, confirms the willingness to supply Karing Hearts Cardiology, PLLC with N-13 Ammonia for cardiac PET perfusion for the calendar years of 2013 and 2014 at the proposed Johnson City location. Precision Nuclear, LLC operates a cyclotron on-site in nearby Gray, Tennessee.

Ownership

- Karing Heart Cardiology, PLLC is owned by cardiologist Dr. Jeffrey Schoondyke, MD.
- The Tennessee Secretary of State web-site indicates Karing Hearts Cardiology, PLLC is an active one member professional limited liability company formed in February 2011.

Facility Information

- Karing Hearts Cardiology currently leases 8,083 SF in the "701" building, which is a 23,000 SF building owned by Dr. Jefferey Schoondyke and his wife.
- The practice will dedicate 905 SF out of the 8,083 SF for PET services. The PET service area will allocate a 328 SF Cardiac PET room, and a 147 SF PET Control Room.
- The cardiology practice and PET service will share the following areas: Patient Prep Room; Hot Lab (Nuclear Med); Entry; Reception; Sub Waiting; and Hallways/Circulation.
- A table is included on page 8 of the application describing the square footage and percent allocated in each space of the proposed PET service.
- A floor plan drawing is included as Attachment B.IV. - Floor Plan to the original application.

Service Area Demographics

Karing Hearts Cardiology's declared service area includes Carter, Unicoi and Washington Counties.

The total population of the service area is estimated at 206,246 residents in calendar year (CY) 2014 increasing by approximately 4.0% to 214,561 in CY 2018.

- The range of growth is 0.7% in Carter County to 6.0% in Washington County.
- Washington County is projected to have the largest population (136,509 or 65% of total service area population) of the service area counties followed by Carter County (57,680 or 27% of total).
- The overall statewide population is projected to grow by 3.7% from 2014 to 2018.
- The latest 2013 percentage of the proposed service area population enrolled in the TennCare program is approximately 16.5%. The statewide enrollment proportion is 18.3%.

Source: The University of Tennessee Center for Business and Economic Research Population Projection Data Files, Reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.

PET equipment utilization recently reported by the HSDA for PET units in the primary service area is shown below:

PET Utilization in the 3-County Tennessee PSA

			2010	2011	2012	'10-'12	2012
County	**Provider**	**Fixed Units**	**Procs.**	**Procs.**	**Procs.**	**% change**	**% of Standard***
Washington	JCMC	1	1,769	1,542	1,234	-30.2%	77%
Washington	LifeScan TN, LLC	2	342	514	623	+82%	19.4%
Totals		**3 fixed**	**2,111**	**2,056**	**1,857**	**-12.3%**	**46.4%**

**The State Health Plan Certificate of Need PET Standards and Criteria indicate "applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to 1,600 procedures per year by the second year of service and every year thereafter."*

- Utilization of PET services appears to be trending slightly downward for the service area from 2,111 procedures in 2010 to 1,857 procedures in 2012, or -12%.
- None of the 3 fixed PET units in the three (3) county service area achieved the minimum of 1,600 procedures per year in 2012.

- There are currently 2 fixed PET units in Washington County.
- Wellmont Cardiology was approved by the Agency in July 2013 to move one of the two PET scanner systems from LifeScan Tennessee, LLC to Kingsport, TN (CN1304-013A) in Sullivan County.

Projected utilization for the applicant's PET/CT scanner is provided below:

Karing Hearts Cardiology Projected PET Utilization

	(1st Year) 2015	Yr. One % of 1,000 Standard	(2nd year) 2016	Year Two % of 1,600 standard
PET Procedures	678	67.8%	745	46.5%

Source: Karing Hearts Cardiology, CN1311-046

- In Year One, the applicant projects to perform 678 procedures, or 67.8% of the 1,000 PET procedure minimum.
- In Year Two, the applicant projects to perform 745 procedures, or 46.5% of the 1,600 standard.

Project Cost

Major costs are:

- The largest cost of the proposed project is the lease of the Cardiac PET system at $144,000 or 37% of total project cost.
- The next largest cost is $109,035 for the Fair Market Value (FMV) of leased space or 28% of total project cost.
- Another major cost is $100,000 for construction cost or 26% of total cost.
- For other details on Project Cost, see the Project Cost Chart on page 41 of the original application.
- The applicant expects the 905 SF renovation cost per square foot to be $110.50.
- In a letter dated November 13, 2013, the Architectural Firm Mitch Cox Companies states the proposed facility will meet all applicable current building codes.

Historical Data Chart

- According to the Historical Data Chart, Karing Hearts Cardiology reported the following net operating loss/income after capital expenditures; a net operating loss of ($101,175) in 2011, and net operating income of $11,841 in 2012; and $96,497 for 2013.

Projected Data Chart

The Projected Data Chart for the PET service reflects $2,063,832 in total gross revenue on 678 procedures during the first year of operation and $2,155,285 on 754 procedures in Year Two. The Projected Data Chart reflects the following:

- Net operating income less capital expenditures for the applicant will equal $48,868 in Year One decreasing to $40,049 in Year Two.
- Net operating revenue after bad debt, charity care, and contractual adjustments is expected to be approximately 54% of total gross revenue in both Year One and Year Two, totaling $1,114,469 and $1,163,854, respectively.
- Gross operating margin is expected to be 2.4% in Year One and 1.9% Year Two.

Charges

In Year One of the proposed project, the average charge per procedure information is as follows:

- The proposed average gross charge per PET procedure is $3,044; however the net charge per procedure is $1,644.
- According to the HSDA Medical Equipment Registry, the gross charge of $3,044 is below the PET scanner 1st Quartile Charge of $3,668 for the Year 2012.

Gross Charges per Procedure/Treatment
By Quartiles
2012

Equipment Type	1st Quartile	Median	3rd Quartile
PET Scanner	$3,667.96	$4,497.71	$6,304.71

Medicare/TennCare Payor Mix

- The expected payor mix for cardiac PET in Year 1 includes 60% for Medicare and 6% for TennCare
- Karing Hearts Cardiology, PLLC contracts with all TennCare MCOs in the service area: BlueCare, United Healthcare (AmeriChoice), and TennCare Select, as well as Virginia Medicaid.

Financing

- A November 12, 2013 letter from Bobby A. Brown, Senior Vice President of Mountain Commerce Bank noted the availability of a 10-year term loan of $139,000.00 at a 4.75% interest rate to cover the cost of the project. The remaining $252,585 in project cost will be funded out of operations.

- Karing Hearts Cardiology, PLLC's unaudited financial statements dated October 31, 2013 reported $62,686 in checking/savings, total current assets of $72,670, total current liabilities of $34,448 and a current ratio of 2.11:1.

- Current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

The proposed staffing for the cardiac PET service is displayed in the table below:

Position Type	FTE
Registered Nurse	.5
Nuclear Medicine Technologist	1.0

Licensure/Accreditation

- Karing Hearts Cardiology is accredited by the Intersocietal Commission on Accreditation.

If approved, the applicant will seek a transfer agreement with MSHA's Johnson City Medical Center, which the applicant states is less than one mile away along the same highway.

The applicant has submitted the required information on corporate documentation, lease, and manufacturer's quote including maintenance contract, and FDA approval. Staff will have a copy of these documents available for member reference at the meeting. Copies are also available for review at the Health Services and Development Agency's office.

Should the Agency vote to approve this project, the CON would expire in two years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:

There are no other Letters of Intent, pending or denied applications, or outstanding Certificates of Need for this applicant.

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent, denied applications, or pending applications for other health care organizations proposing this type of service.

Outstanding Certificates of Need

Wellmont Cardiology Services, CN1304-013A, has an outstanding Certificate of Need which will expire on September 1, 2015. It was approved at the July 24, 2013 Agency meeting for the initiation of cardiac PET services by acquiring an existing PET system located in Gray, Tennessee and relocating the unit to 2050 Meadowview Parkway, Kingsport (Sullivan County), TN 37660. The applicant will establish an outpatient diagnostic center (ODC) if required by the Tennessee Department of Health. The estimated project cost is **$1,074,000.00. Project Status:** *Project Status: Wellmont Cardiology Services expects to initiate PET services in March 2014.*

Molecular Imaging Alliance, CN1304-014A, has an outstanding Certificate of Need which will expire on September 1, 2015. It was approved at the July 24, 2013 Agency meeting for the relocation of an Outpatient Diagnostic Center (ODC) with cardiac PET scanning from 830 Suncrest Drive, Suite 1, Gray (Washington County), TN to 701 N. State of Franklin Road, Suite 1, Johnson City (Washington County), TN. The estimated project cost is **$495,339.00. Project Status:** *If Karing Hearts Cardiology, CN1311-046, is approved at the February 26, 2014 Agency meeting, Molecular Imaging Alliance, CN1304-014 will be surrendered.*

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PME
(02/13/14)

LETTER OF INTENT

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Johnson City Press, which is a newspaper of general circulation in Washington County, Tennessee, on or before November 10, 2013, for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. Sections 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Karing Hearts Cardiology, PLLC (a private professional medical practice), owned and managed by Jeffrey Schoondyke, M.D. (a physician), intends to file an application for a Certificate of Need to initiate Cardiac PET services and to acquire Cardiac PET equipment, at its practice office at 701 State of Franklin Road, Suite 2, Johnson City, TN 37604, at a capital cost estimated at $500,000.

The project will not add or discontinue any other significant health service at this medical practice; and the project does not include any other type of major medical equipment.

The anticipated date of filing the application is on or before November 15, 2013. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

(Signature)	(Date)	(E-mail Address)
	11-8-13	jwdsg@comcast.net

COPY
-Application
Karing Harts Cardiology

CN1311-046

DSG Development Support Group

NOV 15 '13 PM 2:26

November 15, 2013

Melanie M. Hill, Executive Director
Tennessee Health Services and Development Agency
Frost Building, Third Floor
161 Rosa Parks Boulevard
Nashville, Tennessee 37203

RE: CON Application for Cardiac PET Service, by Karing Hearts Cardiology
Johnson City, Washington County

Dear Mrs. Hill:

This letter transmits an original and two copies of the subject application. The affidavit and filing fee are enclosed.

This application intends to replace CN1304-014, which was approved by the HSDA Board in July. That CON was for the relocation of Molecular Imaging Alliance's existing Cardiac PET ODC from Gray to Johnson City, into a medical office building occupied by Karing Hearts Cardiology--the physician practice that has always been the largest referral source for this ODC.

The owner of the ODC, Mr. Robert Gregory, now wants to exit the business and turn it over to Karing Hearts Cardiology. Karing Hearts has decided to offer this service as a service of the practice, rather than to acquire ODC ownership. The purpose of this application is simply to authorize Cardiac PET as a service of the practice; and when that occurs, Mr. Gregory will turn in CN1304-014 to be voided.

Because this is no more than a change in applicant for a type of equipment and service approved in two prior reviews, the applicant requests Consent Calendar review.

I am the contact person for this project. Byron Trauger is legal counsel. Please advise me of any additional information you may need. We look forward to working with the Agency on this project.

Respectfully,

John Wellborn

John Wellborn
Consultant

4219 Hillsboro Road, Suite 203
Nashville, TN 37215

jwdsg@comcast.net

Tel 615.665.2022
Fax 615.665.2042

KARING HEARTS CARDIOLOGY, PLLC

CERTIFICATE OF NEED APPLICATION TO ACQUIRE A CARDIAC PET SCANNER FOR THE PRACTICE

Johnson City, Washington County
Filed April 2013

PART A

1. Name of Facility, Agency, or Institution

Karing Hearts Cardiology Cardiac PET Service		
Name		
701 State of Franklin Road, Suite 2		Washington
Street or Route		*County*
Johnson City	TN	37604
City	*State*	*Zip Code*

2. Contact Person Available for Responses to Questions

John Wellborn		Consultant	
Name		*Title*	
Development Support Group		jwdsg@comcast.net	
Company Name		*E-Mail Address*	
4219 Hillsboro Road, Suite 210	Nashville	TN	37215
Street or Route	*City*	*State*	*Zip Code*
CON Consultant	615-665-2022	615-665-2042	
Association With Owner	*Phone Number*	*Fax Number*	

3. Owner of the Facility, Agency, or Institution

Karing Hearts Cardiology, PLLC		
Name		
701 State of Franklin Road, Suite 2		Washington
Street or Route		*County*
Johnson City	TN	37604
City	*State*	*Zip Code*

4. Type of Ownership or Control (Check One)

A. Sole Proprietorship		F. Government (State of TN or Political Subdivision)	
B. Partnership		G. Joint Venture	
C. Limited Partnership		H. Limited Liability Company	
D. Corporation (For-Profit)		I. Other (Specify): Professional	
E. Corporation (Not-for-Profit)		Limited Liability Company	x

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS

5. *Name of Management/Operating Entity (If Applicable)* NA

Name		
Street or Route		*County*
City	*State*	*Zip Code*

6. *Legal Interest in the Site of the Institution (Check One)*

A. Ownership		D. Option to Lease	
B. Option to Purchase		E. Other (Specify):	
C. Lease of 5 Years	x		

7. *Type of Institution (Check as appropriate—more than one may apply)*

A. Hospital (Specify): General		I. Nursing Home	
B. Ambulatory Surgical Treatment Center (ASTC) Multi-Specialty		J. Outpatient Diagnostic Center	
C. ASTC, Single Specialty		K. Recuperation Center	
D. Home Health Agency		L. Rehabilitation Center	
E. Hospice		M. Residential Hospice	
F. Mental Health Hospital		N. Non-Residential Methadone	
G. Mental Health Residential Facility		O. Birthing Center	
H. Mental Retardation Institutional Habilitation Facility (ICF/MR)		P. Other Outpatient Facility (Specify):	
		Q. Other (Specify): Private Practice	x

8. *Purpose of Review (Check as appropriate—more than one may apply*

A. New Institution		G. Change in Bed Complement Please underline the type of Change: Increase, Decrease, Designation, Distribution, Conversion, Relocation	
B. Replacement/Existing Facility		H. Change of Location	
C. Modification/Existing Facility		I. Other (Specify):	
D. Initiation of Health Care Service as defined in TCA Sec 68-11-1607(4) (Specify) Cardiac PET	x		
E. Discontinuance of OB Service			
F. Acquisition of Equipment	x		

9. *Bed Complement Data* *NA*

(Please indicate current and proposed distribution and certification of facility beds.)

	Current Licensed Beds	CON approved beds (not in service)	Staffed Beds	Beds Proposed (Change)	TOTAL Beds at Completion
A. Medical					
B. Surgical					
C. Long Term Care Hosp.					
D. Obsetrical					
E. ICU/CCU					
F. Neonatal					
G. Pediatric					
H. Adult Psychiatric					
I. Geriatric Psychiatric					
J. Child/Adolesc. Psych.					
K. Rehabilitation					
L. Nursing Facility (non-Medicaid certified)					
M. Nursing Facility Lev. 1 (Medicaid only)					
N. Nursing Facility Lev. 2 (Medicare only)					
O Nursing Facility Lev. 2 (dually certified for Medicare & Medicaid)					
P. ICF/MR					
Q. Adult Chemical Dependency					
R. Child/Adolescent Chemical Dependency					
S. Swing Beds					
T. Mental Health Residential Treatment					
U. Residential Hospice					
TOTAL					

10. Medicare Provider Number:	103G706288
Certification Type:	group medical practice
11. Medicaid Provider Number:	1523022
Certification Type:	group medical practice

12. & 13. See page 4

A.12. IF THIS IS A NEW FACILITY, WILL CERTIFICATION BE SOUGHT FOR MEDICARE AND/OR MEDICAID?

This is an existing physician practice that participates in both Medicare and TennCare/Medicaid, including Medicaid in adjoining Virginia.

A.13. IDENTIFY ALL TENNCARE MANAGED CARE ORGANIZATIONS / BEHAVIORAL HEALTH ORGANIZATIONS (MCO'S/BHO'S) OPERATING IN THE PROPOSED SERVICE AREA. WILL THIS PROJECT INVOLVE THE TREATMENT OF TENNCARE PARTICIPANTS? Yes IF THE RESPONSE TO THIS ITEM IS YES, PLEASE IDENTIFY ALL MCO'S WITH WHICH THE APPLICANT HAS CONTRACTED OR PLANS TO CONTRACT.

DISCUSS ANY OUT-OF-NETWORK RELATIONSHIPS IN PLACE WITH MCO'S/BHO'S IN THE AREA.

Table One: Contractual Relationships with Service Area MCO's	
Available TennCare MCO's / Medicaid	**Applicant's Relationship**
BlueCare	contracted
United Community Healthcare Plan (formerly AmeriChoice)	contracted
TennCare Select	contracted
Virginia Medicaid	contracted

SECTION B: PROJECT DESCRIPTION

B.I. PROVIDE A BRIEF EXECUTIVE SUMMARY OF THE PROJECT NOT TO EXCEED TWO PAGES. TOPICS TO BE INCLUDED IN THE EXECUTIVE SUMMARY ARE A BRIEF DESCRIPTION OF PROPOSED SERVICES AND EQUIPMENT, OWNERSHIP STRUCTURE, SERVICE AREA, NEED, EXISTING RESOURCES, PROJECT COST, FUNDING, FINANCIAL FEASIBILITY AND STAFFING.

Proposed Services and Equipment

• LifeScan Tennessee, LLC, dba Molecular Imaging Alliance, owns and operates a licensed Outpatient Diagnostic Center ("ODC") in Gray, Tennessee, in northwest Washington County. It provides cardiac PET services. It is the only cardiac PET facility in Upper East Tennessee. In July 2013, it was unanimously granted CN1304-014 to relocate with one leased Cardiac PET unit to a smaller office space 10 miles east, at 701 State of Franklin Road, Johnson City, TN. This location adjoins the physician practice of Karing Hearts Cardiology, which has always been the largest referral source for this Cardiac PET ODC. Implementation of that relocation is suspended, pending HSDA decision on this application.

• The ODC's owner, Mr. Robert Gregory, is seeking to exit the ODC business and to terminate its lease of the PET unit it now operates, without implementing the ODC at the new location in Johnson City. The physicians of Karing Hearts Cardiology seek to lease that same PET unit to offer it as a service of their practice, so that the approved relocation of the service from Gray to Johnson City may be implemented. They do not want to acquire and operate the ODC that holds the CON (which could be done without further CON approval). If Karing Hearts Cardiology is approved to offer this service and implements that approval, then Molecular Imaging Alliance will turn in CN1304-014 to be voided.

• The project will serve counties already approved for this type of service. It will not change the scope of services, or the costs already approved for this service. This will be the third CON review for the Cardiac PET service, so consent calendar review is respectfully requested.

• The cardiac PET service will be housed in medical practice space, and will utilize practice staff consisting of a nuclear medicine tech, an RN (half time) and a receptionist (half time).

Ownership Structure

• The CON applicant is Karing Hearts Cardiology, PLLC, a Johnson City cardiology practice owned by Dr. Jeffrey Schoondyke, M.D. A second cardiologist, Dr. Melanie Davidson, joined the practice in late 2013. She is also an established cardiologist in the service area.

Service Area

• The Cardiac PET ODC was granted CON approval in CY2007, to provide cardiac PET services to all of Upper East Tennessee. It has been doing that for more than five years.

This project under physician ownership will not serve counties that were not included in prior reviews of this project. Its Tennessee primary service area (85.3% of referrals) will be Washington, Carter, and Unicoi Counties, with additional patients coming from Sullivan, Greene, and Johnson Counties, and from other nearby counties and States.

Need & Existing Resources

• This new application is required to convert the approved cardiac PET service from an ODC-based service to a physician practice-based service, at the same site the HSDA approved in July. The need for cardiac PET services in this area was reviewed and established at the time of the ODC's original approval in 2007 (CN0701-010). The need to relocate the service from Gray to Johnson City, with one cardiac PET unit, was established by unanimous approval of CN1304-014 in July 2013.

• The need for filing another application arises from the CON holder's recent decision to exit the Outpatient Diagnostic Center business without implementing CN1304-014, and the need of physicians and patients in the service area for continuing access to cardiac PET scanning, at the location approved four months ago. Karing Hearts is willing to lease the cardiac PET equipment directly, and to offer the service at the previously approved location, but as part of its practice rather than as a separate licensed facility.

• Since 2007, the ODC in Gray has been the Upper East Tennessee region's only source of cardiac-specific PET units. It has operated two cardiac PET units. In July 2013, Wellmont Cardiology Services was granted CON approval to acquire one of the two units and move it to Kingsport; and that is being implemented. At the same meeting, LifeScan was approved to move its Molecular Imaging Associates ODC with the remaining PET unit to Johnson City. This new application is to convert the ODC-based PET to a physician-based PET. It will still be one of only two cardiac PET units available in Upper East Tennessee.

Project Cost, Funding, Financial Feasibility, and Staffing

• The estimated project cost for CON purposes, which includes an estimation of the value of leased space, and equipment (not capital cost items), is $391,585. The actual capital cost for moving the PET system and renovating the proposed site will be only $138,550. It will be funded by a loan from a local bank.

• Even at a future rate of growth much less than its 17% annual average growth since 2009, this service will operate with a positive margin from the time it opens as a physician office-based service. It is an established service in the region. The applicant cardiology group in the past has referred the great majority of its utilization, so its core of demand will not be diminished by this change of organization and ownership. It will be within an established cardiology practice that serves Medicare, TennCare, Medicaid, and uninsured patients.

• Under this medical practice's ownership, the cardiac PET service will have exactly the same staff that it has today, and was approved to have in CN1304-014. It will have the same Medical Director, Dr. Jeffrey Schoondyke. Its cardiac studies will be performed with the assistance of a nuclear medicine tech, and an RN and receptionist shared with the medical practice.

B.II. PROVIDE A DETAILED NARRATIVE OF THE PROJECT BY ADDRESSING THE FOLLOWING ITEMS AS THEY RELATE TO THE PROPOSAL.

B.II.A. DESCRIBE THE CONSTRUCTION, MODIFICATION AND/OR RENOVATION OF THE FACILITY (EXCLUSIVE OF MAJOR MEDICAL EQUIPMENT COVERED BY T.C.A. 68-11-1601 *et seq.)* INCLUDING SQUARE FOOTAGE, MAJOR OPERATIONAL AREAS, ROOM CONFIGURATION, ETC.

Ownership and Scope of the Project

The CON applicant is Karing Hearts Cardiology, PLLC, a cardiology practice established in Johnson City by Dr. Jeffrey Schoondyke, M.D., who is its sole member. A second cardiologist, Dr. Melanie Davidson, has recently joined the practice. She is also an established cardiologist in the service area.

The applicant proposes to lease from LifeScan Leasing, LLC (an equipment vendor) the GE Advance Nxi Cardiac PET system that the ODC in Gray currently leases, and to install it in the same part of the applicant's practice space that received approval as Cardiac PET ODC space under CN1304-014, just four months ago.

The proposed new location is very close to Johnson City Medical Center. There, it will be more convenient to patients referred from the Johnson City medical community, and it will be under the supervision of Karing Hearts Cardiology physicians.

Karing Hearts Cardiology will utilize the service for its patients. A lesser number of additional procedures will be performed for patients referred from other practices, unless Tennessee Department of Health licensure rules preclude such referrals to a PET service that is not licensed as an ODC.

The Project Site (Same As In Approved CN1304-014)

The project's address will be Karing Hearts Cardiology, 701 State of Franklin Road, Suite 2, Johnson City, Tennessee 37604. The building is owned by Dr. Jeffrey Schoondyke and his wife. The owners lease one end of the building to Karing Hearts Cardiology, PLLC, the medical practice of Dr. Schoondyke and Dr. Melanie Davidson.

Their medical practice occupies Suites One Two, and Three of the building, using Suite Two as its main entrance and address. Other non-related entities occupy other suites in the building.

Design of the Project

The practice itself will be providing the service, in space it already leases from the building owner. The "701" building has approximately 23,000 SF of space. Karing Hearts Cardiology currently leases 8,083 SF of the building. The proposed service will use a small amount of "dedicated" space and will share several support spaces with other services of the practice. Table Two-A below indicates the applicant's space allocation for PET services. The PET and its control room are exclusively for use by PET patients; the other spaces are shared with other patients so they were allocated to this project at 50% of their floor space. The total space allocation for the project is 905 SF. (This was used to prorate the practice's expenses for this project, in the Projected Data Chart .)

Table Two-A: Medical Practice Space Allocated to Cardiac PET Services			
Space	**Square Footage**	**Percent Allocated**	**SF Allocation**
Cardiac PET Room	328 SF	100%	328 SF
PET Control Room	147.25 SF	100%	147.25 SF
Patient Prep Room	165 SF	50%	82.5 SF
Hot Lab (Nuclear Med.)	56.25	50%	28.125 SF
Entry	215.25 SF	50%	107.625 SF
Reception	90.25 SF	50%	45.125 SF
Sub waiting	192 SF	50%	96 SF
Hallways / Circulation	141 SF	50%	70.5 SF
Total			***905.125 SF***

Source: Medical practice Management

The Cardiac PET service will utilize a cardiac PET camera room with an adjoining control room, and will share use of the practice's nuclear medicine "hot lab", a patient prep/uptake room, an entry, a reception/checkout desk, a sub-waiting area, and circulation space within the practice. The cardiac PET camera room, nuclear medicine room, and patient prep/uptake room are expensive to renovate, due to the need for radiation shielding in their walls, and strengthened floor footings in the camera room. A floor plan for the office's PET services area and adjoining medical spaces is provided in Attachment B.IV in this application.

At Gray, the ODC that offers this service is accredited for Nuclear Medicine/Positive Emission Tomography (PET) services by the Intersocietal Accreditation Commission (IAC). The applicant medical practice will seek to maintain that accreditation at its Johnson City site when it takes over the service from the ODC.

Construction Cost

No new construction is required. An estimated 556 SF of the allocated area of 905 SF will require heavy renovation (shielding and some reinforced floor footings); the other 349 SF will be finished as medical office space, requiring only minor renovation. The overall renovation cost will be only $110.50 PSF.

Table Two-B: Construction Costs of This Project		
	SF of Renovation	**SF of New Construction**
Square Feet Allocated	905 SF	0
Construction Cost	$100,000	0
Constr. Cost PSF Allocated	$110.50	0

Implementation Schedule and Hours of Operation

If granted CON approval before the end of February 2014, this relocation project can be open for patient service prior to December 31, 2014. Its first full calendar year will be CY2015. The current hours of operation (scheduled service) for the ODC in Gray are from 7 AM to 5 PM, on weekdays. This schedule will continue at the Karing Hearts Cardiology location.

Project Cost and Financing

The project's cost for CON review purposes--which includes the value of leased space and leased equipment--is estimated at $391,585. The applicant's actual capital cost (for project design, construction, equipment, and the CON process) will be only $138,550. This amount is available from a local bank (please see the bank's confirmation letter in the Attachments).

APPLICANTS WITH HOSPITAL PROJECTS (CONSTRUCTION COST IN EXCESS OF $5 MILLION) AND OTHER FACILITY PROJECTS (CONSTRUCTION COST IN EXCESS OF $2 MILLION) SHOULD COMPLETE THE SQUARE FOOTAGE AND COSTS PER SQUARE FOOTAGE CHART....

Not applicable.

PLEASE ALSO DISCUSS AND JUSTIFY THE COST PER SQUARE FOOT FOR THIS PROJECT.

This project requires only renovation of existing space, at an overall average cost of only $110.50 PSF. The tables below compare that to renovation costs for the other two approved cardiac PET CON's in this region, and for several approved ODC's.

ODC renovation projects completed in 2008-2012 ranged from $52-$196 PSF construction cost, according to data from the HSDA Registry. Although the HSDA Registry did not compile a similar table for 2010-2012 due to the small number of ODC projects (5) completed in 2012, the Registry has supplied construction cost data for several of those projects; see Table Three-B below. Karing Hearts Cardiology's projected renovation cost of $110.50 PSF compares well to these projects' costs.

Table Three-A: Outpatient Diagnostic Center Construction Cost PSF
Years: 2008-2010

	Renovated Construction	New Construction	Total Construction
1st Quartile	$51.55/sq ft	none	$51.55/sq ft
Median	$122.15/sq ft	none	$122.15/sq ft
3rd Quartile	$196.46/sq ft	none	$196.46/sq ft

Source: HSDA Registry. CON approved applications for years 2008 through 2010

Table Three-B: Outpatient Diagnostic Center Construction Cost PSF
Years: 2012

CON	ODC / Provider	Renovation Area	Construction Cost / sq ft
CN1010-046	Murfreesboro Diagnostic Imaging	9,587 SF	$122.15/sq ft
CN1010-047	Cleveland Imaging	911 SF	$269.91/sq ft
CN1103-008	E. TN Community Open MRI	795 SF	$160.38/sq ft
CN1110-039	St. Thomas OP Imaging	7,737 SF	$159.69/ sq ft
CN1110-039	Wellmont Cardiology Services Cardiac PET, Kingsport	2,080 SF	$250 PSF
CN1304-014	Molecular Imaging ODC	847 SF	$177 PSF
This Project	Karing Hearts Cardiology	905 SF	$110.50 PSF

Source: HSDA Registry. CON approved ODC projects involving only renovation.

IF THE PROJECT INVOLVES NONE OF THE ABOVE, DESCRIBE THE DEVELOPMENT OF THE PROPOSAL.

Not applicable.

B.II.B. IDENTIFY THE NUMBER AND TYPE OF BEDS INCREASED, DECREASED, CONVERTED, RELOCATED, DESIGNATED, AND/OR REDISTRIBUTED BY THIS APPLICATION. DESCRIBE THE REASONS FOR CHANGE IN BED ALLOCATIONS AND DESCRIBE THE IMPACT THE BED CHANGE WILL HAVE ON EXISTING SERVICES.

Not applicable; no inpatient beds are affected by the project.

B.II.C. AS THE APPLICANT, DESCRIBE YOUR NEED TO PROVIDE THE FOLLOWING HEALTH CARE SERVICES (IF APPLICABLE TO THIS APPLICATION):

1. **ADULT PSYCHIATRIC SERVICES**
2. **ALCOHOL AND DRUG TREATMENT ADOLESCENTS >28 DAYS**
3. **BIRTHING CENTER**
4. **BURN UNITS**
5. **CARDIAC CATHETERIZATION SERVICES**
6. **CHILD AND ADOLESCENT PSYCHIATRIC SERVICES**
7. **EXTRACORPOREAL LITHOTRIPSY**
8. **HOME HEALTH SERVICES**
9. **HOSPICE SERVICES**
10. **RESIDENTIAL HOSPICE**
11. **ICF/MR SERVICES**
12. **LONG TERM CARE SERVICES**
13. **MAGNETIC RESONANCE IMAGING (MRI)**
14. **MENTAL HEALTH RESIDENTIAL TREATMENT**
15. **NEONATAL INTENSIVE CARE UNIT**
16. **NON-RESIDENTIAL METHADONE TREATMENT CENTERS**
17. **OPEN HEART SURGERY**
18. **POSITIVE EMISSION TOMOGRAPHY**
19. **RADIATION THERAPY/LINEAR ACCELERATOR**
20. **REHABILITATION SERVICES**
21. **SWING BEDS**

A. Reason For Filing This Application

The project is for a Johnson City cardiology practice to acquire and operate a cardiac PET system for its patients, at the time the nearby ODC that currently provides that service ceases to operate.

There are several things that make this project unique with respect to "demonstrating need". Briefly put, the need for the service, and its need to be at this same address in Johnson City, have been established by two prior CON reviews, the most recent of which was only four months ago, was unopposed, and received unanimous approval. This service is being reviewed again in a third application, only because the applicant physician group proposes to be the provider, replacing the ODC that was granted the two prior Certificates of Need. HSDA staff advises that this makes it a new project from a legal viewpoint. The ODC supports this application, because the ODC intends to close in the near future without implementing its CON to relocate to Johnson

City, and wants the service to continue to be available to area patients. So the following special facts should be considered:

(a) A cardiac PET service was approved by CN0701-010 as a needed service for multiple counties in the Upper East Tennessee region, including those proposed to be served in this application.

(b) This service has been operating five years in this area, serving hundreds of patients a year, most of whom were referred by the practice that is the applicant in this project.

(c) Cardiac PET continues to be a standard of diagnostic care for certain coronary conditions, with usage increasing steadily as it becomes physically more accessible than in the past.

(c) This service, now offered in nearby Gray, is already medically supervised by the cardiologist who is filing this application to move it to Johnson City.

(e) The service's relocation to Johnson City (as an ODC), to the same room and building in which this application proposes to offer the service, was approved unanimously by the HSDA only a few months ago (CN1304-014).

B. The Need for Cardiac PET Scanning and Its Difference from Conventional PET/CT

Cardiac PET studies and conventional PET/CT studies are both types of nuclear medicine tests, in which faintly radioactive substances with short half-lives are injected into the patient, revealing important diagnostic information as they move through the body and are tracked and measured on imaging equipment and computers. However, cardiac PET and conventional PET/CT studies differ significantly in several ways.

First, they differ in their scope of use. Conventional PET/CT units are almost entirely devoted to oncology and neurology studies (although they can be fitted with a software/hardware retrofit to do cardiac PET procedures). Cardiac PET systems are used for two purposes currently. One purpose is to identify blockages or circulation defects in heart arteries ("myocardial perfusion studies"). These studies provide such good diagnostic information that many patients can avoid having a subsequent diagnostic cardiac catheterization examination, which is an invasive surgical procedure that costs

more and imposes higher risks. The other purpose is to measure "myocardial viability" in patients with left ventricular dysfunction, to determine their candidacy for revascularization (arterial graft surgery). The cardiac PET test can show whether the heart tissue at the proposed site of surgery is too compromised to sustain and maintain an arterial graft. If it is, the patient can be spared an expensive, uncomfortable, and ultimately ineffective major surgery.

A second difference between conventional PET/CT and cardiac PET is their cost; a cardiac PET system is much less expensive. For example, in CY2012, HSDA Registry data shows that area PET units as a group billed an average gross charge of $5,223 per PET scan. That year the ODC's cardiac PET studies were billed at an average gross charge of only $1,829--approximately one-third of the average of all PET units.

A third difference is that cardiac PET technology uses only two radiopharmaceuticals at the present time: either ammonia (N-13) or rubidium (R-82). The first has a half-life of only 10 minutes. The second has a half-life of only 75 seconds. This means that as a practical matter, the radiopharmaceutical supplier must be within a short drive of the cardiac PET unit, if not in the same building or room. The Gray ODC has been using N-13, supplied by a cyclotron in their building in Gray. The supplier can continue to provide N-13 to both scanners when they move to Karing Hearts in Johnson City, merely by manufacturing sufficient amounts of N-13 so that the required dosage is sufficient by the time it is administered. For example, if the delivery trip time plus administration of the pharmaceutical take 30 minutes, then an amount with the strength of eight doses of N-13 might be sent, so that after its radioactivity diminishes by 50% every 10 minutes, 1 full dose will remain available for injection. ("Dose" here is used in an illustrative sense; a patient may receive two doses as defined by nuclear medicine protocols.)

C. The Difference Between Cardiac PET and SPECT Nuclear Medicine Studies

For a large number of patients being diagnosed at a cardiology office, SPECT studies are scheduled to obtain diagnostic information similar to that provided by cardiac PET. However, it is increasingly accepted that cardiac PET yields superior diagnostic information.

The value of cardiac PET as a superior option to nuclear medicine SPECT studies (especially for patients of large body mass) has been consistently demonstrated by an array of clinical studies. Excerpts from several professional articles about its efficacy and cost savings are provided in the Attachments to this application--from the Journal of Nuclear Medicine, the Journal of American Cardiology, the Journal of Nuclear Cardiology, and Image (a professional magazine). As the case has built for this modality, more cardiology practices have begun to utilize it. The studies show that for patients considered likely to have coronary artery disease, myocardial perfusion PET is superior to SPECT in terms of image quality, interpretive certainty, and diagnostic accuracy. This is because cardiac PET has higher photon counts, improved spatial resolution, and attenuation correction in its images. With such improved information, the cardiologist can better evaluate the need (and probable efficacy) of additional "downstream" tests and interventions such as cardiac catheterizations and coronary artery bypass surgery.

D. The Need to Relocate The Service to Johnson City and to This Medical Practice

The applicant ODC is currently located in Gray, Tennessee, in the far western part of Washington County. The referring cardiologists who generate most of its utilization are based in Johnson City, in eastern Washington County.

There are three reasons for changing location of this service to Johnson City, and to Karing Hearts Cardiology's practice office.

First, the relocation will improve its physical accessibility to referring physicians, who must be onsite at the PET for medical supervision during their patients' cardiac PET scans. Being in Johnson City will shorten drive times for most of the ODC's patients and physicians. For example, the average drive time from Johnson City Medical Center to Gray is 12.3 miles (18 minutes), whereas the drive time from the Medical Center to the proposed site at 701 State of Franklin Road in Johnson City is only 0.8 miles (2 minutes). Round-trip savings for a physician coming from the Medical Center area will be approximately half an hour each time. For example, Dr. Jeffrey Schoondyke's practice is located in the 701 Building. With the service in his practice office, Dr. Schoondyke and his patients can eliminate drive time for the test. Even if no other physician ever refers to

the service, the time saved just for Dr. Schoondyke and Dr. Davidson and their hundreds of patients will be significant.

The second reason to relocate is to lower operating costs. The ODC that offers the service presently, and was planning to move it to Johnson City, has more space than it needs at Gray and was seeking to lower its lease costs with a relocation of only one PET system (its second PET system is being sold to another provider). If the service is transferred to Karing Hearts Cardiology as the provider, and placed in its practice office in space already under lease, the service will not have any rent payment, as the ODC would have. *(Note: rent is included as an expense on the Projected Data Chart in this application because the HSDA staff requires an allocation of existing rent to such a project, even though implementing the project will not increase existing rent.)*

The third and most compelling reason why this project is needed is that the ODC which is the Johnson City area's only source of cardiac PET services intends to go out of business, as soon as someone else can take over the equipment lease and provide the service. The logical successor to this ODC is the physician group that provides most of its referrals and provides its medical direction already, especially since their office was the place to which the ODC was approved to move in CN1304-014 last July. There is no health planning reason why this clinically significant service should be rendered unavailable to the eastern half of Upper East Tennessee, or should be kept in Gray; Karing Hearts Cardiology is prepared to ensure its continued availability for its patients, at a more convenient location.

E. Project Consistency With Health Planning Goals

The Guidelines for PET are addressed in a later section of this application. However, CON review involves many considerations other than the review criteria in the State Health Plan. This project, which allows Karing Hearts Cardiology to acquire and operate an existing cardiac PET service as a logical successor to its current operator, furthers several good planning objectives. Examples include the following.

1. Non-proliferation of services and major medical equipment: For reasons explained above, although a CON review is needed for a change in the legal provider

entity, in fact this cardiac PET system and service are not "new" in the sense of being additions of technology to the service area. They exist now; and they have been approved to move to the location that is proposed in Johnson City, albeit under other ownership. So this project cannot be said to duplicate existing services.

2. No change in service area: the equipment's relocation will not cause it to serve any counties that are not already being served by the ODC in Gray.

3. Consistent with prior CON approvals: Existence of the service, and its relocation to this same address in Johnson City, have already been approved in two prior CON reviews.

4. Improves accessibility: Implementing a prior-approved relocation to Johnson City will increase the convenience of the service for both patients and physicians.

6. Improves efficiency: A cardiac PET test visit takes about an hour and 15 minutes, compared to three to six hours for a SPECT test visit. Switching to cardiac PET saves patients and their supervising physicians substantial time. The applicant believes that replacement of SPECT with cardiac PET will continue to increase if its location becomes more convenient for physicians and patients to use it, and as the service area population ages.

7. Cost savings: Studies are showing that cardiac PET rules out coronary artery bypass surgeries and cardiac catheterizations for many patients, and reduces the costs of care in such cases by as much as 30%. (See articles in the Attachments). So if the relocation from Gray to Johnson City boosts utilization of cardiac PET, the healthcare system will experience savings. In addition, the project cost for adding this to an existing physician office, without having to construct and license a separate Outpatient Diagnostic Center, or to pay lease expenses, offers a small cost advantage over the ODC relocation recently approved in CN1304-014.

B.II.D. DESCRIBE THE NEED TO CHANGE LOCATION OR REPLACE AN EXISTING FACILITY.

Not applicable.

B.II.E. DESCRIBE THE ACQUISITION OF ANY ITEM OF MAJOR MEDICAL EQUIPMENT (AS DEFINED BY THE AGENCY RULES AND THE STATUTE) WHICH EXCEEDS A COST OF $1.5 MILLION; AND/OR IS A MAGNETIC RESONANCE IMAGING SCANNER (MRI), POSITRON EMISSION TOMOGRAPHY (PET) SCANNER, EXTRACORPOREAL LITHOTRIPTER AND/OR LINEAR ACCELERATOR BY RESPONDING TO THE FOLLOWING:

1. For fixed site major medical equipment (not replacing existing equipment):
- **a. Describe the new equipment, including:**
  1. **Total Cost (As defined by Agency Rule);**
  2. **Expected Useful Life;**
  3. **List of clinical applications to be provided; and**
  4. **Documentation of FDA approval.**
- **b. Provide current and proposed schedule of operations.**

2. For mobile major medical equipment:
- **a. List all sites that will be served;**
- **b. Provide current and/or proposed schedule of operations;**
- **c. Provide the lease or contract cost;**
- **d. Provide the fair market value of the equipment; and**
- **e. List the owner for the equipment.**

3. Indicate applicant's legal interest in equipment (e.g., purchase, lease, etc.) In the case of equipment purchase, include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

• The PET scanner being relocated is a 2002 GE Advance Nxi PET scanner system including the camera, workstation, software, water chiller unit, lead door, in-lab furniture, and miscellaneous items in the lab and control room.

• The PET system was manufactured in 2002; its value is estimated at $350,000.

• Its expected useful life is five years.

• It will perform cardiac PET examinations for both perfusion and blockage evaluations.

• Its current hours of operation in Gray are 7 am to 5 pm weekdays; this schedule will be maintained at its proposed new location in Johnson City.

• The applicant will lease the system. A draft of the lease applicable to this relocation is included in the Attachments.

B.III.A. ATTACH A COPY OF THE PLOT PLAN OF THE SITE ON AN 8-1/2" X 11" SHEET OF WHITE PAPER WHICH MUST INCLUDE:

1. **SIZE OF SITE (IN ACRES);**
2. **LOCATION OF STRUCTURE ON THE SITE;**
3. **LOCATION OF THE PROPOSED CONSTRUCTION; AND**
4. **NAMES OF STREETS, ROADS OR HIGHWAYS THAT CROSS OR BORDER THE SITE.**

PLEASE NOTE THAT THE DRAWINGS DO NOT NEED TO BE DRAWN TO SCALE. PLOT PLANS ARE REQUIRED FOR ALL PROJECTS.

See Attachment B.III.A.

B.III.B.1. DESCRIBE THE RELATIONSHIP OF THE SITE TO PUBLIC TRANSPORTATION ROUTES, IF ANY, AND TO ANY HIGHWAY OR MAJOR ROAD DEVELOPMENTS IN THE AREA. DESCRIBE THE ACCESSIBILITY OF THE PROPOSED SITE TO PATIENTS/CLIENTS.

The project site is very accessible to this practice's service area. Johnson City is the largest community in Washington County and is a tertiary healthcare referral destination, well known to patients living throughout the service area. The project site is reasonably accessible to all parts of upper East Tennessee by Federal and State highways. It is within minutes of I-26, which connects quickly to I-81, the major east-west highway in that region. US Highways 23 and 321, and Highways 67, 173, and 37 also provide access to other parts of the primary service area. Table Four below shows the average distances and drive times to principal cities in the project's primary and secondary service areas, and to the nearest alternative source of cardiac PET scans.

Table Four: Mileage and Drive Times Between Project and Major Communities in and Near the Primary Service Area

From project at 701 N. State of Franklin Road, Johnson City, to:	County	Distance	Drive Time
Primary Service Area			
1. Elizabethton	Carter	12.8 mi.	23 min.
2. Erwin	Unicoi	18.2 mi	24 min.
3. Johnson City (the Medical Center)	Washington	0.8 mi.	2 min.
Secondary Service Area			
4. Greeneville	Greene	29.2 mi.	38 min.
5. Mountain City	Johnson	45.8 mi.	68 min.
5. City of Kingsport (center)	Sullivan	23.5 mi.	29 min.
6. Wellmont Cardiology Services Cardiac PET service, Kingsport	Sullivan	18.6 mi.	20 min.

Source: Google Maps, April and November 2013.

B.IV. ATTACH A FLOOR PLAN DRAWING FOR THE FACILITY WHICH INCLUDES PATIENT CARE ROOMS (NOTING PRIVATE OR SEMI-PRIVATE), ANCILLARY AREAS, EQUIPMENT AREAS, ETC.

See attachment B.IV.

IV. FOR A HOME CARE ORGANIZATION, IDENTIFY

1. **EXISTING SERVICE AREA (BY COUNTY);**
2. **PROPOSED SERVICE AREA (BY COUNTY);**
3. **A PARENT OR PRIMARY SERVICE PROVIDER;**
4. **EXISTING BRANCHES AND/OR SUB-UNITS; AND**
5. **PROPOSED BRANCHES AND/OR SUBUNITS.**

Not applicable. The application is not for a home care organization.

C(I) NEED

C(I).1. DESCRIBE THE RELATIONSHIP OF THIS PROPOSAL TO THE IMPLEMENTATION OF THE STATE HEALTH PLAN AND TENNESSEE'S HEALTH: GUIDELINES FOR GROWTH.

A. PLEASE PROVIDE A RESPONSE TO EACH CRITERION AND STANDARD IN CON CATEGORIES THAT ARE APPLICABLE TO THE PROPOSED PROJECT. DO NOT PROVIDE RESPONSES TO GENERAL CRITERIA AND STANDARDS (PAGES 6-9) HERE.

B. APPLICATIONS THAT INCLUDE A CHANGE OF SITE FOR A HEALTH CARE INSTITUTION, PROVIDE A RESPONSE TO GENERAL CRITERION AND STANDARDS (4)(a-c).

Project-Specific Review Criteria: PET Scanners

The State Health Plan contains CON review criteria for PET scanners. The applicant believes that they were intended primarily to guide review of proposed new PET units in a service area, i.e., projects in which an additional PET is proposed for an area, or in which a prior approved PET is proposing a relocation that will result in a new service area.

Neither factor is present in this project. This project is to relocate an existing cardiac PET system under new ownership, not to add a system to the area. The relocation is within the same county. At the applicant's practice, the cardiac PET will serve only counties that are already being served by the current provider of the service. That current provider has requested that the practice take over the service. Therefore, applying "need" criteria as if this service did not already exist, or would be duplicative, does not seem logical. This is only a change of provider of an existing service, with a simultaneous relocation to a premises already approved for the service's current owner. The applicant therefore asks that the criteria be applied prudently.

Following this page is a copy of the PET Standards and Criteria from the 2009 State Health Plan. Following that document are the applicant's responses to those criteria, numbered to correspond to the State Health Plan document.

APPENDIX A. Revised and Updated Standards and Criteria for Positron Emission Tomography (PET) services

STATE OF TENNESSEE

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

POSITRON EMISSION TOMOGRAPHY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Positron Emission Tomography (PET) services. Existing providers of PET services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for PET services.

These standards and criteria are effective immediately as of November 18, 2009, the date of approval and adoption by the governor of the State Health Plan. Applications to provide PET services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Positron Emission Tomography (PET): A noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body (source: The Centers for Medicare and Medicaid Services). PET differs from other nuclear medicine modalities in the type of radiation emitted and in the type of scanner required to detect it. By measuring the distributions of certain radiotracers in the body some time after they have been administered, PET can be used to diagnose physical abnormalities and to study body functions in normal subjects.

PET Unit: Diagnostic equipment (often referred to as a "scanner") that uses a positron camera (tomograph) to produce cross-sectional tomographic images (this process is often referred to as a "scan"). The images are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-(F-18) Fluoro-D-Glucose (FDG) which are administered intravenously to the patient. The radioactive tracers may be

produced on-site, e.g. with a cyclotron, or may be ordered from commercial distributors. As a result, factors such as equipment cost, geographic distribution and availability of distributors, and other related factors (regulatory compliance/certification) should be considered by the Agency in its review of all PET applications.

First developed in the 1970s, initial PET scanners were dedicated machines performing only that service. PET scanners can be either fixed (stationary) or mobile. Current technological adaptations include hybrid machines, such as combined PET-CT (computed tomography) scanners that are capable of performing a variety of nuclear medicine studies.

PET Procedure: A PET diagnostic scan or combination of scans performed on a single patient during a single visit. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition.

Stationary PET Unit: A non-moveable PET unit housed at a single permanent location.

Mobile PET Unit: A PET unit and transporting equipment that is moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the Continental United States.

Capacity: The measure of the maximum number of PET scans per PET unit per year based upon the type of PET equipment to be used (i.e., stationary or mobile).

Stationary PET Unit Capacity: Total capacity of a stationary PET unit is 2,000 procedures per year and is based upon a daily operating efficiency of eight procedures per day x 250 days of operation per year. The optimal efficiency for a stationary PET unit is 80 percent of total capacity, or 1,600 procedures per year.

Mobile PET Unit Capacity: Total capacity of a mobile PET scanner is 400 annual procedures per day of operation per week and is based upon a daily operating efficiency of at least eight (8) procedures per day x number of days in operation per week x approximately 50 weeks per year. The optimal efficiency of a mobile PET unit is based upon the number of days per week that it is in operation. For each day of operation per week, the optimal efficiency is 320 procedures per year, or 80 percent of total capacity.

PET Unit Service Area: The counties, or portions thereof, representing a reasonable area in which a health care institution intends to provide PET unit services, including, but not limited to, oncology and cardiology diagnostic and treatment services, and in which at least 75% of its service recipients reside. A PET unit should be located at a site that allows reasonable access for residents of the service area.

Service Area Capacity: The estimate of the number of PET units needed in a given service area. The estimate is based upon an optimal efficiency of 1,600 procedures per year for a stationary PET unit and an optimal efficiency of 320 annual procedures per day of operation per week for a mobile PET unit, and the quantitative estimate of the number

of patients who potentially could benefit from PET diagnostic services, especially those patients pertaining to the following categories:

- those patients where the use of PET unit services is essential to the diagnosis, treatment, or surveillance of cancer, including, but not limited to, diagnosis codes approved by the Centers for Medicare and Medicaid Services (CMS);
- those patients who are either non-emergent candidates for open heart surgery or therapeutic cardiac catheterization procedures;
- those patients with a diagnosis of partial complex epilepsy for whom surgical intervention is being considered; and
- any other patient population that may benefit from the accessibility to stationary or mobile PET unit services as a result of expanded clinical applications and changes in the reimbursement of PET service by third party payors, including those pertaining to programs administered by the CMS.

In addition to the above determinants of service area capacity, applicants should consider demographic patterns, including the results of estimates of population health risk factors and population-based cancer, heart disease, or other applicable clinical incidence rates. The data should be consistent with data prepared by the Tennessee Department of Health. Applicants should also document the extent, if any, of diagnostic oncology, cardiac and neurological medical services in the proposed service area in its determination of the need for PET unit services.

Standards and Criteria

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

   For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed

service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

   Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

   Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

   The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.

   a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

   b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

   c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

   a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

   b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

   c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

APPLICANT'S RESPONSES TO THE CRITERIA

Note: For brevity, the CON PET criteria in the preceding section are paraphrased below in bold letters. The applicant has added sub-parts "A", "B", etc. to the numbered State Plan criteria when responding to multiple paragraphs of some criteria.

1A. For a "new stationary PET unit", projected annual utilization should be a minimum of 1,000 procedures in Year One and a minimum of 1,600 procedures every year thereafter.

Response: This criterion is not applicable, because this is not a new unit for the area. It is a proposed change of provider/owner for an existing, previously approved cardiac PET unit and service. Its use will be restricted to cardiac procedures, for the patients of a single practice. It is not ever likely to perform the minimum numbers of procedures recommended for a general PET unit without such restrictions. If it continues to grow at 10% a year, it will reach a rate of 1,600 annual procedures in CY2024, its tenth year of operation.

IB. Demographic Data--An application for a stationary unit should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category)ICD-9).

Response: This is not applicable, because if is part of criterion #1 for "applicants proposing a new stationary PET unit..." or "a mobile PET unit", neither of which is proposed in this application. However, in the Frequent Charge chart in this application, the applicant's utilization by ICD-9 is projected for CY2015 and CY2016. Ample demographic information on the service area is presented. However, the service's utilization has not been projected by population-based factors, but rather from trending past increases in demand for the service within the medical practice which seeks to offer the service.

2A. Applicants "applying for a proposed new PET unit" should document its accessibility to 75% of the service area population.

Response: Not applicable because a new PET unit is not being proposed. However, the project is very accessible to 75% of the service area population. Approximately 85.3% of its patients will come the primary service area of Washington, Carter, and Unicoi Counties. The principal communities in all three of those counties are less than thirty minutes' average drive time of Karing Hearts Cardiology, the project site. See Table Four in the application.

2B. Identify PET unit locations, capacity, and utilization in non-Tennessee counties in the service area, and discuss project impact on them.

Response: Not applicable because a new PET unit is not being proposed, and also because there are no non-Tennessee counties in the primary service area.

3. Document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

Response: There is no other cardiac PET provider in the primary service area, with whom the applicant could share this service. The only other cardiac PET unit in the region is the Wellmont Health System in Kingsport, in adjoining Sullivan County. It is not as physically close to primary service area residents as Gray or Johnson City. It is not available to patients who are not in the practice of Wellmont Cardiology Services. It is also going to be used at full capacity by patients of Wellmont Cardiology, within three years. So alternate services in the region are not as accessible or available. They are likely to be comparable in terms of continuity, cost, and quality of care, for most referred patients.

4. (This criterion is not applicable because it pertains only to a proposed new mobile PET.)

5A. Need for "one additional stationary PET unit in an area" is likely if the utilization of existing PET providers was at or above 80% of their total capacity (i.e., at or above 1,600 procedures annually), as reported to HSDA most recently.

Response: Not applicable. The applicant is not proposing to open an additional PET unit in the area. The applicant's medical practice is proposing to acquire and operate the only PET service currently approved within in the Karing Hearts Cardiology primary service area.

In Section C(I)5 of this application, the applicant provides historic utilization for the ODC in Gray (Washington County), which provides the only such service in the primary service area. It attained 668 procedures in CY2012. The section also provides the PET utilization of all PET providers in or near the Tennessee primary service area. Only one has reported to the HSDA an annual utilization of 1,600 or more procedures.

5B. Applicants (for "one additional stationary unit in a service area") should perform at least 1,000 and 1,600 procedures per year in the first two years, respectively.

Response: This criterion is not applicable, because this is not an additional unit for the area. It is a proposed change of provider/owner for an existing, previously approved cardiac PET unit and service. Its use will be restricted to cardiac procedures, for the patients of a single practice. If it achieves an annual growth rate of 10% a year, it will reach a rate of 1,600 annual procedures in CY2024, its tenth year of operation.

6a. The PET unit must be FDA-certified for clinical use.

Response: Complies; documentation is provided in Attachment B.II.A.3.

6b. The PET's physical environment must conform to applicable Federal standards, manufacturer's specifications, and licensing requirements.

Response: Compliance in this regard is established by the architect's letter in Atttachment C, Economic Feasibility-1, attesting to intended compliance with applicable codes, standards, and licensing requirements.

6c. The applicant should demonstrate how emergencies will be managed in conformity with accepted medical practice.

Response: Please see the applicant's emergency response protocols, in Attachment C, Need--1A.

6d. The applicant should establish protocols assuring that procedures are medically necessary and are not unnecessarily duplicative.

Response: Please see the applicant's medical necessity protocols, in in Attachment C, Need--1A.

6e. Medical Direction should be provided by a licensed physician Board certified in either Nuclear Medicine or Diagnostic Radiology. Licensure should be in place for handling radioactive pharmaceuticals and medical isotopes. Interpreting physicians should have documented experience and training, credentialing, and/or Board certification in the appropriate specialty and in the use and interpretation of PET procedures.

Response: Dr. Jeffrey Schoondyke, whose C.V. is in the Attachments, is a Board certified cardiologist who has been Medical Director for the cardiac PET service at the Gray ODC for several years. He is trained and highly experienced in the use and interpretation of cardiac PET studies. Dr. Schoondyke will continue to be Medical Director of the cardiac PET service when it moves to his practice office in Johnson City. His practice already holds a license for handling radioactive substances, for nuclear medicine studies of other types that the practice currently performs.

6f. Applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. The medical director should be an active member of the medical staff of the hospital with which the agreement is made.

Response: Dr. Jeffrey Schoondyke is an active member of the medical staff of Johnson City Medical Center, with which Karing Hearts Cardiology will have a transfer agreement if this project is approved.

7. Submission of data to the HSDA

Response: The applicant commits to comply with the requirement for timely submission of the identified data to the HSDA Equipment Registry.

Factors for Special Consideration

8a. Service to Medically Underserved Areas

Response: Medically Underserved Areas/Populations are areas or populations designated by the Federal Health Resources and Services Administration (HRSA) as having too few primary care providers, high infant mortality, high poverty and/or high elderly population.

At the end of the Attachment labeled "Miscellaneous Information", the applicant provides documentation of each Federally-designated "Medically Underserved Area" ("MUA") in the project's primary service area. These lists are from the HRSA website. They identify the following MUA's:

- Carter County
- Unicoi County
- Within Washington County: MCD's 90940/District 5; 91510/District 8; 91700 District 9. These are in the county's Bethesda Division Service Area.

8b. Higher than Average State Rate of Heart Disease

Response: The applicant is not claiming this special circumstance at this time. This is neither a new service for the area, nor an additional unit for the area; so justification of this type should not be deemed necessary.

8c. Safety Net Hospital; Children's Hospital; or Comprehensive Cancer Program

Response: The application is not by a safety net hospital, a children's hospital, or a hospital with a comprehensive cancer program.

8d. Commitment to Contract with One or More TennCare MCO's and to participate in Medicare.

Response: The payor mix of Dr. Schoondyke's practice, from which the cardiac PET's referrals will come, is currently approximately 60% Medicare and 6% TennCare. His practice contracts with all available MCO's in the area.

The Framework for Tennessee's Comprehensive State Health Plan

Five Principles for Achieving Better Health

The following Five Principles for Achieving Better Health serve as the basic framework for the State Health Plan. After each principle, the applicant states how this CON application supports the principle, if applicable.

1. Healthy Lives

The purpose of the State Health Plan is to improve the health of Tennesseans.
Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

This project reflects a collaboration between Karing Hearts Cardiology and Molecular Imaging Alliance ODC in Gray (which is going to close in the near future), to find a way to continue offering cardiac PET services to the Johnson City area and to the primary service area now being served. Approving Karing Hearts Cardiology as the successor to Molecular in this service will ensure its continued availability. Relocating Molecular's remaining cardiac PET unit to Johnson City, closer to physicians and patients who utilize it, will greatly improve access to this testing modality, which in turn will increase its utilization, providing improved diagnostic information and significant cost savings in terms of subsequent interventional care.

2. Access to Care

Every citizen should have reasonable access to health care.
Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

Geography has been a barrier to optimal use of the cardiac PET scanning systems at the ODC in Gray. The service is located miles outside the medical centers of the service area, making it less accessible for patients and physicians and limiting its use. This project will address that issue, improving access for patients who live in this sector of Upper East Tennessee and seek healthcare in Johnson City.

3. Economic Efficiencies

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the

continued development of the state's health care system. **The State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.**

This is an opportunity for the State regulatory system to assist providers in making a needed service more accessible, so that its technology can be more completely and efficiently utilized.

4. Quality of Care

Every citizen should have confidence that the quality of health care is continually monitored and that standards are adhered to by health care providers. **Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.**

The project will bring this modality much closer to its current and potential users (cardiologists and their patients in Johnson City). That will make it more readily and efficiently accessible. The applicant believes that increased accessibility to cardiac PET scanning will increase its use, leading to better diagnostic data, which can improve diagnosis and intervention for this large group of patients.

5. Health Care Workforce

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. **The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.**

The project is neutral with respect to training of health professionals. It is not a training/rotation site for any schools at the present time. The applicant would welcome such an affiliation, should it be offered.

C(I).2. DESCRIBE THE RELATIONSHIP OF THIS PROJECT TO THE APPLICANT'S LONG-RANGE DEVELOPMENT PLANS, IF ANY.

The applicant is a private physician practice that does not prepare formal long-range development plans.

C(I).3. IDENTIFY THE PROPOSED SERVICE AREA AND JUSTIFY THE REASONABLENESS OF THAT PROPOSED AREA. SUBMIT A COUNTY-LEVEL MAP INCLUDING THE STATE OF TENNESSEE CLEARLY MARKED TO REFLECT THE SERVICE AREA. PLEASE SUBMIT THE MAP ON A 8-1/2" X 11" SHEET OF WHITE PAPER MARKED ONLY WITH INK DETECTABLE BY A STANDARD PHOTOCOPIER (I.E., NO HIGHLIGHTERS, PENCILS, ETC.).

A service area map and a map showing the location of the service within the State of Tennessee are provided as Attachments C, Need--3 at the back of the application.

The cardiac PET service area, under the control of Karing Hearts Cardiology, will continue to be most of the counties around Johnson City that are now being served by the Gray ODC. Table Five on the next page shows Karing Heart's current primary service area counties for referrals to cardiac PET. They have generated, and will continue to generate, approximately 85% of the practice's cardiac PET referrals.

Within the primary service area, approximately 58.2% of the practice's YTD2013 referrals to cardiac PET were residents of Washington County, where the service will continue to be located if this application is approved. Another 27.1% of its cardiac PET referrals were residents of adjoining Carter and Unicoi Counties.

Karing Heart's secondary service area for this type of patient, contributing 14.7% of the practice's cardiac PET referrals, includes Sullivan, Greene, Johnson, Hawkins, and Grainger Counties, and unidentified counties in nearby areas of Virginia and North Carolina.

Table Five: Patient Origin
Karing Heart Cardiology Referrals for Cardiac PET Scans
CY2013 / CY2015-CY2016

County	Karing Heart Referrals for Cardiac PET, Jan-Oct 2013	Percent of Total	Cumulative Percent of Total	Year One CY2015 Cardiac PET Scans	Year Two CY2016 Cardiac PET Scans
Primary Service Area (PSA) Counties					
Washington	221	58.2%	58.2%	394.3	433.3
Carter	73	19.2%	77.4%	130.2	143.1
Unicoi	30	7.9%	85.3%	53.5	58.8
PSA Subtotal	*324*	*85.3%*		*578.1*	*635.2*
Secondary Service Area (SSA) Counties and States					
Sullivan	24	6.3%	91.6%	42.8	47.1
Greene	9	2.4%	93.9%	16.1	17.6
Johnson, Hawkins, Grainger	11	2.9%	96.8%	19.6	21.6
Other States	12	3.2%	100.0%	21.4	23.5
SSA Subtotal	*56*	*14.7%*		*99.9*	*109.8*
Grand Total	*380*	*100.0%*		*678.0*	*745.0*

Source: Cardiac PET scan patient origin from practice records; projections by practice management.
Note: Scans calculated to tenths to document round numbers of Years One and Two total utilization projections.

C(I).4.A DESCRIBE THE DEMOGRAPHICS OF THE POPULATION TO BE SERVED BY THIS PROPOSAL.

Table Six, following this page, provides the demographic profile for the three Tennessee counties in this project's primary service area. Basically, area residents are somewhat older and lower income than the State average.

The counties in the primary service area (all in Tennessee) have a median age of 42.1 compared to the State median age of 38.0; and 17.0% of area residents are elderly compared to 14.6% Statewide. In addition, the service area's elderly population is projected to increase 4.4% in size over the next four years. The aging of the population will continue to increase the need for high-quality, accessible, affordable cardiac care in this area. This project helps meet all three needs.

Also, the service area's median income of $36,505 is 17% below the State average. But a smaller percent of service area residents (12.0%) are below the poverty level than in Tennessee as a whole (16.9%). The service area's TennCare population is 16.5% of all residents, compared to 18.3% Statewide. The project will be accessible to low-income residents of the service area. Approximately 66% of patients served by the project will be Medicare or Medicaid/TennCare enrollees (60% Medicare; 6% TennCare).

Table Six: Demographic Characteristics of Primary Service Area Counties Karing Hearts Cardiology's Cardiac PET Service 2013-2017

Demographic	Washington County	Carter County	Unicoi County	PRIMARY SERVICE AREA	STATE OF TENNESSEE
Median Age-2010 US Census	39.3	42.2	44.9	42.1	38.0
Total Population-2013	128,537	57,228	18,334	204,099	6,528,014
Total Population-2017	136,509	57,548	18,487	212,544	6,772,022
Total Population-% Change 2013 to 2017	6.2%	0.6%	0.8%	4.1%	3.7%
Age 65+ Population-2013	21,028	10,710	3,015	34,753	950,177
% of Total Population	16.4%	18.7%	16.4%	17.0%	14.6%
Age 65+ Population-2017	21,430	10,978	3,874	36,282	1,072,143
% of Population	15.7%	19.1%	21.0%	17.1%	15.8%
Age 65+ Population-% Change 2013-2017	1.9%	2.5%	28.5%	4.4%	12.8%
Median Household Income	$42,104	$32,148	$35,265	$36,506	$43,989
TennCare Enrollees (7/13)	19,004	11,262	3,505	33,771	1,193,721
Percent of 2013 Population Enrolled in TennCare	14.8%	19.7%	19.1%	16.5%	18.3%
Persons Below Poverty Level (2013)	22,237	12,590	3,795	38,622	1,103,234
Persons Below Poverty Level As % of Population (US Census)	17.3%	22.0%	20.7%	12.0%	16.9%

Sources: TDH Population Projections, 2013; U.S. Census QuickFacts; TennCare Bureau. PSA data is unweighted average or total of county data. NR means not reported in U.S. Census source document.

C(I).4.B. DESCRIBE THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION, INCLUDING HEALTH DISPARITIES, THE ACCESSIBILITY TO CONSUMERS, PARTICULARLY THE ELDERLY, WOMEN, RACIAL AND ETHNIC MINORITIES, AND LOW-INCOME GROUPS. DOCUMENT HOW THE BUSINESS PLANS OF THE FACILITY WILL TAKE INTO CONSIDERATION THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION.

The applicant's practice had demonstrated accessibility to these consumer groups. More than half (60%) of Karing Hearts Cardiology's patients YTD were Medicare and another 6% were TennCare/Medicaid. The practice will continue to be accessible to these groups. The projected charity care for the cardiac PET service is 3% of gross charges. The practice's current management works with each patient to pay as he or she is able.

C(I).5. DESCRIBE THE EXISTING OR CERTIFIED SERVICES, INCLUDING APPROVED BUT UNIMPLEMENTED CON'S, OF SIMILAR INSTITUTIONS IN THE SERVICE AREA. INCLUDE UTILIZATION AND/OR OCCUPANCY TRENDS FOR EACH OF THE MOST RECENT THREE YEARS OF DATA AVAILABLE FOR THIS TYPE OF PROJECT. BE CERTAIN TO LIST EACH INSTITUTION AND ITS UTILIZATION AND/OR OCCUPANCY INDIVIDUALLY. INPATIENT BED PROJECTS MUST INCLUDE THE FOLLOWING DATA: ADMISSIONS OR DISCHARGES, PATIENT DAYS, AND OCCUPANCY. OTHER PROJECTS SHOULD USE THE MOST APPROPRIATE MEASURES, E.G., CASES, PROCEDURES, VISITS, ADMISSIONS, ETC.

The only cardiac PET service in the primary service area of Karing Hearts Cardiology is the ODC service in Gray, that this application seeks to acquire and convert to a practice-based service.

Table Seven below shows that ODC's historic utilization from 2009 to 2012. Its growth has been exceptionally strong despite its remote location midway between the region's two largest medical care centers. Over the period 2009-2012, utilization of the service increased more than 17% per year (compound annual growth rate or CAGR).

Table Seven: Utilization of Molecular Imaging Alliance Cardiac PET 2009-2012

	2009	2010	2011	2012
Procedures	411	342	514	668
% Annual Change	--	- 16.8%	+50.3%	+30.0%
Numeric Annual Change	--	-69	+172	+154
% Change 2009-2012	--	--	--	+62.5%
Numeric Change 2009-12	--	--	--	+257
Compound Annual Growth Rate 2009-2012	--	--	--	>17%

Source: HSDA Registry 2009-11; Molecular Imaging Alliance records, 2012.

The following page provides the HSDA Registry's data for all PET units in the primary and secondary service area--only one of which (LifeScan, dba Molecular Imaging Associates) is equipment dedicated to cardiac PET. To the applicant's best knowledge, only one other PET in this area is even able to perform cardiac PET studies--the mobile PET operated by Holston Valley Medical Center. However, its first priority is to meet high demand for oncology PET scans; Wellmont Cardiology Service's recently approved application for Cardiac PET stated that the mobile unit limits cardiac studies to only 300 patients per year.

Health Care Providers that Utilize PET Scanners

County	Provider Type	Provider	Year	Number of	Mobile ?	Mobile Days Used	Total Procedures	Total Gross Charges	Average Gross Charge
Greene	HOSP	Laughlin Memorial Hospital, Inc.	2009	1	Mobile (Part)	1 day/week	436	$1,375,036.00	$3,153.75
Greene	HOSP	Laughlin Memorial Hospital, Inc.	2010	1	Mobile (Part)	2 days/week	456	$1,928,760.00	$4,229.74
Greene	HOSP	Laughlin Memorial Hospital, Inc.	2011	1	Mobile (Part)	2 days/week	430	$1,815,432.00	$4,221.93
Greene	HOSP	Laughlin Memorial Hospital, Inc.	2012	1	Mobile (Part)	1 day/week	351	$1,483,770.00	$4,227.26
Hamblen	HOSP	Morristown-Hamblen Hospital	2009	1	Mobile (Part)	2 days/week	341	$1,534,500.00	$4,500.00
Hamblen	HOSP	Morristown-Hamblen Hospital	2010	1	Mobile (Part)	3 days/week	296	$987,000.00	$3,334.46
Hamblen	HOSP	Morristown-Hamblen Hospital	2011	1	Mobile (Part)	2 days/week	317	$1,313,875.00	$4,144.72
Hamblen	HOSP	Morristown-Hamblen Hospital	2012	1	Mobile (Part)	2 days/week	405	$1,808,573.00	$4,465.61
Sullivan	HOSP	Bristol Regional Medical Center	2009	1	Mobile (Part)	2 days/week	464	$2,067,596.00	$4,456.03
Sullivan	HOSP	Bristol Regional Medical Center	2010	1	Mobile (Part)	2 days/week	435	$1,840,351.00	$4,230.69
Sullivan	HOSP	Bristol Regional Medical Center	2011	1	Mobile (Part)	2 days/week	466	$2,080,050.00	$4,463.63
Sullivan	HOSP	Bristol Regional Medical Center	2012	1	Mobile (Part)	2 days/week	460	$2,105,911.00	$4,578.07
Sullivan	HOSP	Holston Valley Medical Center	2009	1	Mobile (Part)	3 days/week	1263	$5,626,711.00	$4,455.04
Sullivan	HOSP	Holston Valley Medical Center	2010	1	Mobile (Part)	3 days/week	1381	$6,154,683.00	$4,456.69
Sullivan	HOSP	Holston Valley Medical Center	2011	1	Mobile (Part)	3 days/week	1501	$6,636,461.00	$4,421.36
Sullivan	HOSP	Holston Valley Medical Center	2012	1	Mobile (Part)	3 days/week	1677	$7,542,662.00	$4,497.71
Sullivan	HOSP	Indian Path Medical Center	2009	1	Mobile (Part)	1 day/week	138	$931,955.00	$6,753.30
Sullivan	HOSP	Indian Path Medical Center	2010	1	Mobile (Part)	1 day/week	154	$1,061,218.00	$6,891.03
Sullivan	HOSP	Indian Path Medical Center	2011	1	Mobile (Part)	1 day/week	133	$1,000,842.00	$7,525.13
Sullivan	HOSP	Indian Path Medical Center	2012	1	Mobile (Part)	1 day/week	143	$1,202,291.00	$8,407.63
Washington	HOSP	Johnson City Medical Center	2009	1	Fixed	0	2121	$14,209,376.00	$6,699.38
Washington	HOSP	Johnson City Medical Center	2010	1	Fixed	0	1769	$12,136,169.00	$6,860.47
Washington	HOSP	Johnson City Medical Center	2011	1	Fixed	0	1542	$11,506,728.00	$7,462.21
Washington	HOSP	Johnson City Medical Center	2012	1	Fixed	0	1234	$10,275,190.00	$8,326.73
Washington	ODC	LifeScan Tennessee, LLC	2009	2	Fixed	0	411	$1,336,879.00	$3,252.75
Washington	ODC	LifeScan Tennessee, LLC	2010	2	Fixed	0	342	$587,344.00	$1,717.38
Washington	ODC	LifeScan Tennessee, LLC	2011	2	Fixed	0	514	$1,623,309.46	$3,158.19
Washington	ODC	LifeScan Tennessee, LLC	2012	2	Fixed	0	623	$1,139,661.00	$1,829.31
		2009 Service Area Total		**8**			**5174**	**$27,082,053.00**	$5,234.26
		2010 Service Area Total		**8**			**4833**	**$24,695,525.00**	$5,109.77
		2011 Service Area Total		**8**			**4903**	**$25,976,697.46**	$5,298.12
		2012 Service Area Total		**8**			**4893**	**$25,558,058.00**	**$5,223.39**

Medical Equipment Registry - 4/24/2013

C(I).6. PROVIDE APPLICABLE UTILIZATION AND/OR OCCUPANCY STATISTICS FOR YOUR INSTITUTION FOR EACH OF THE PAST THREE (3) YEARS AND THE PROJECTED ANNUAL UTILIZATION FOR EACH OF THE TWO (2) YEARS FOLLOWING COMPLETION OF THE PROJECT. ADDITIONALLY, PROVIDE THE DETAILS REGARDING THE METHODOLOGY USED TO PROJECT UTILIZATION. THE METHODOLOGY MUST INCLUDE DETAILED CALCULATIONS OR DOCUMENTATION FROM REFERRAL SOURCES, AND IDENTIFICATION OF ALL ASSUMPTIONS.

This application is for a new service for the applicant's medical practice, so there is no historical utilization at this location for the practice per se. However, Karing Hearts Cardiology has been the major referral source for the service at its Gray facility; and the practice's principal physician, Dr. Schoondyke, is the ODC's Medical Director for the service. Therefore, the ODC's historical utilization is shown in Section C(I)5 above.

Future utilization for the cardiac PET as a practice-based service has been projected very conservatively, assuming utilization only by Drs. Schoondyke and Davidson, the two cardiologists of the practice. The projection is shown in Table Eight below. The methodology was as follows.

Dr. Schoondyke made 380 referrals to the Gray ODC, for cardiac PET studies from January through October 2013. This annualizes to a projection of 456 annual referrals (380 X12/10 = 456) for CY2013. The practice has just added Dr. Davidson, who brings an established patient base to the practice, and it is projected that her new patients will increase referrals for cardiac PET by a minimum of 25% in her first year of practice. In addition, despite the service's current inconvenient location, the area demand for cardiac PET tests at Gray has been growing at a rate of 17% a year. So it is reasonable to expect an additional annual increase of 10%, for Dr. Schoondyke's own referrals, from CY2013 to CY2014. The 10% annual increase, plus the one-time 25% increase from Dr. Davidson's patients, will result in a 35% increase of referrals in CY2014--or a total of 616 PET referrals. After 2014, with the service relocated into the Karing Hearts practice office, the applicant expects continuing 10% annual growth, resulting in 678 and 745 cardiac PET studies in Years One and Two of the project.

Table Eight: Projected Referrals for Cardiac PET at Karing Hearts Cardiology 2012-2015				
	CY2013	**CY2014**	**Yr 1-CY2015**	**Yr 2-CY2016**
Procedures	456	616	678	745
Annual Change	--	+35%	+10%	+10%

Source: Practice management.

The cardiac PET's utilization, even at its present inconvenient location, has been increasing at an average rate of 17% since 2009. The projection in Table Eight assumes an average annual increase of only 96.3 referrals a year over the three-year projection period. The applicant considers this projection methodology to be conservative, for several reasons: (a) there is increasing documentation of the clinical benefits of converting most SPECT studies to cardiac PET studies; (b) the cardiac PET will be at a location much more convenient for most service area patients; and (c) providers and insurors will want to achieve the cost savings associated with cardiac PET's ability to rule out the need for some patients to undergo coronary artery bypass surgery.

C(II)1. PROVIDE THE COST OF THE PROJECT BY COMPLETING THE PROJECT COSTS CHART ON THE FOLLOWING PAGE. JUSTIFY THE COST OF THE PROJECT.

• ALL PROJECTS SHOULD HAVE A PROJECT COST OF AT LEAST $3,000 ON LINE F (MINIMUM CON FILING FEE). CON FILING FEE SHOULD BE CALCULATED ON LINE D.

• THE COST OF ANY LEASE (BUILDING, LAND, AND/OR EQUIPMENT) SHOULD BE BASED ON FAIR MARKET VALUE OR THE TOTAL AMOUNT OF THE LEASE PAYMENTS OVER THE INITIAL TERM OF THE LEASE, WHICHEVER IS GREATER. NOTE: THIS APPLIES TO ALL EQUIPMENT LEASES INCLUDING BY PROCEDURE OR "PER CLICK" ARRANGEMENTS. THE METHODOLOGY USED TO DETERMINE THE TOTAL LEASE COST FOR A "PER CLICK" ARRANGEMENT MUST INCLUDE, AT A MINIMUM, THE PROJECTED PROCEDURES, THE "PER CLICK" RATE AND THE TERM OF THE LEASE.

• THE COST FOR FIXED AND MOVEABLE EQUIPMENT INCLUDES, BUT IS NOT NECESSARILY LIMITED TO, MAINTENANCE AGREEMENTS COVERING THE EXPECTED USEFUL LIFE OF THE EQUIPMENT; FEDERAL, STATE, AND LOCAL TAXES AND OTHER GOVERNMENT ASSESSMENTS; AND INSTALLATION CHARGES, EXCLUDING CAPITAL EXPENDITURES FOR PHYSICAL PLANT RENOVATION OR IN-WALL SHIELDING, WHICH SHOULD BE INCLUDED UNDER CONSTRUCTION COSTS OR INCORPORATED IN A FACILITY LEASE.

• FOR PROJECTS THAT INCLUDE NEW CONSTRUCTION, MODIFICATION, AND/OR RENOVATION; DOCUMENTATION MUST BE PROVIDED FROM A CONTRACTOR AND/OR ARCHITECT THAT SUPPORT THE ESTIMATED CONSTRUCTION COSTS.

The architect's letter supporting the construction cost estimate is provided in Attachment C, Economic Feasibility--1.

On the Project Costs Chart, following this response:

Line A.1, A&E fees, were estimated by the project architect.

Line A.2, legal, administrative, and consultant fees, include costs for the CON process and legal services during project planning.

Line A.5, construction cost, was estimated by the project architect at no more than $100,000, for renovation (including shielding) of 905 SF of medical office space.

Line A.6, contingency, was estimated by the architect at 5% of construction cost.

Line A.7 includes for fixed and moveable equipment indicates no costs because this project will relocate an entire cardiac PET system and all related equipment and room furnishings to the new site.

Line A.9 includes such costs as miscellaneous minor equipment and furnishings, and moving expenses.

Line B.1, $109,035, is the fair market value of the facility being leased, calculated in the two alternative ways required by staff rules. The pro rata market value of the space in the building exceeded the lease outlay, and was entered in this line of the Project Cost Chart as required by staff rules.

Lease Outlay Method:

5 years first lease term X 905 SF X $12.00 PSF rate = $54,300 lease outlay over first term.

Pro Rata Building Value Method:

905 SF project / 23,000 SF total building X $2,771,044 actual CY2013 sale price of the building = $109,035 pro rata value of the space to be leased

The applicant again notes that this is a theoretical calculation of lease outlay required by HSDA staff rules. The project is to be placed in space already leased to the medical practice, and about half of that space will be shared with other types of patients. The project will impose no additional lease costs on the practice.

PROJECT COSTS CHART--KARING HEARTS CARDIAC PET SERVICE

A. Construction and equipment acquired by purchase:

1. Architectural and Engineering Fees		$ 10,000
2. Legal, Administrative, Consultant Fees (Excl CON Filing)		15,000
3. Acquisition of Site		0
4. Preparation of Site		0
5. Construction Cost		100,000
6. Contingency Fund		5,000
7. Fixed Equipment (Not included in Construction Contract)		0
8. Moveable Equipment (List all equipment over $50,000)		0
9. Other (Specify)	moving expenses	1,500
	misc. office equipment & furnishings	1,500

B. Acquisition by gift, donation, or lease:

1. Facility (inclusive of building and land)		0
2. Building only	FMV of space being used for PET	109,035
3. Land only		0
4. Equipment (Specify)	lease of Cardiac PET system	144,000
5. Other (Specify)		0

C. Financing Costs and Fees:

1. Interim Financing	$136,000 X 5% X .5 X .75 yrs	2,550
2. Underwriting Costs		0
3. Reserve for One Year's Debt Service		0
4. Other (Specify)		0

D. Estimated Project Cost (A+B+C) 388,585

E. CON Filing Fee 3,000

F. Total Estimated Project Cost (D+E) TOTAL $ 391,585

Actual Capital Cost 138,550
Section B FMV 253,035

C(II).2. IDENTIFY THE FUNDING SOURCES FOR THIS PROJECT.

a. PLEASE CHECK THE APPLICABLE ITEM(S) BELOW AND BRIEFLY SUMMARIZE HOW THE PROJECT WILL BE FINANCED. (DOCUMENTATION FOR THE TYPE OF FUNDING MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND IDENTIFIED AS ATTACHMENT C, ECONOMIC FEASIBILITY--2).

___x__A. Commercial Loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;

_____B. Tax-Exempt Bonds--copy of preliminary resolution or a letter from the issuing authority, stating favorable contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;

_____C. General Obligation Bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting;

_____D. Grants--Notification of Intent form for grant application or notice of grant award;

_____E. Cash Reserves--Appropriate documentation from Chief Financial Officer; or

_____F. Other--Identify and document funding from all sources.

The applicant has arranged for bank loan financing for the actual capital cost of the project (approximately $139,000). Documentation of financing is provided in Attachment C, Economic Feasibility--2.

C(II).3. DISCUSS AND DOCUMENT THE REASONABLENESS OF THE PROPOSED PROJECT COSTS. IF APPLICABLE, COMPARE THE COST PER SQUARE FOOT OF CONSTRUCTION TO SIMILAR PROJECTS RECENTLY APPROVED BY THE HSDA.

This project requires only renovation of existing space, at an overall average cost of only $110.50 PSF. The tables below, repeated from an earlier section of this application, compare that to renovation costs for the other two approved cardiac PET CON's in this region, and for several approved ODC's.

ODC renovation projects completed in 2008-2012 ranged from $52-$196 PSF construction cost, according to data from the HSDA Registry. Although the HSDA Registry did not compile a similar table for 2010-2012 due to the small number of ODC projects (5) completed in 2012, the Registry has supplied construction cost data for several of those projects; see Table Three-B below. Karing Hearts Cardiology's projected renovation cost of $110.50 PSF compares well to these projects' costs.

Table Three-A: Outpatient Diagnostic Center Construction Cost PSF Years: 2008-2010

	Renovated Construction	New Construction	Total Construction
1st Quartile	$51.55/sq ft	none	$51.55/sq ft
Median	$122.15/sq ft	none	$122.15/sq ft
3rd Quartile	$196.46/sq ft	none	$196.46/sq ft

Source: HSDA Registry. CON approved applications for years 2008 through 2010

Table Three-B: Outpatient Diagnostic Center Construction Cost PSF Years: 2012

CON	ODC / Provider	Renovation Area	Construction Cost / sq ft
CN1010-046	Murfreesboro Diagnostic Imaging	9,587 SF	$122.15/sq ft
CN1010-047	Cleveland Imaging	911 SF	$269.91/sq ft
CN1103-008	E. TN Community Open MRI	795 SF	$160.38/sq ft
CN1110-039	St. Thomas OP Imaging	7,737 SF	$159.69/ sq ft
CN1110-039	Wellmont Cardiology Services Cardiac PET, Kingsport	2,080 SF	$250 PSF
CN1304-014	Molecular Imaging ODC	847 SF	$177 PSF
This Project	Karing Hearts Cardiology	905 SF	$110.50 PSF

Source: HSDA Registry. CON approved ODC projects involving only renovation.

C(II).4. COMPLETE HISTORICAL AND PROJECTED DATA CHARTS ON THE FOLLOWING TWO PAGES--DO NOT MODIFY THE CHARTS PROVIDED OR SUBMIT CHART SUBSTITUTIONS. HISTORICAL DATA CHART REPRESENTS REVENUE AND EXPENSE INFORMATION FOR THE LAST THREE (3) YEARS FOR WHICH COMPLETE DATA IS AVAILABLE FOR THE INSTITUTION. PROJECTED DATA CHART REQUESTS INFORMATION FOR THE TWO YEARS FOLLOWING COMPLETION OF THIS PROPOSAL. PROJECTED DATA CHART SHOULD INCLUDE REVENUE AND EXPENSE PROJECTIONS FOR THE PROPOSAL ONLY (I.E., IF THE APPLICATION IS FOR ADDITIONAL BEDS, INCLUDE ANTICIPATED REVENUE FROM THE PROPOSED BEDS ONLY, NOT FROM ALL BEDS IN THE FACILITY).

This is a proposed service for the medical practice, so it does not have an operating history as a practice-based service. See the following pages for a Projected Data Chart, with notes itemizing "Other" expenses.

SUPPLEMENTAL- # 1
November 26, 2013
12:40pm

HISTORICAL DATA CHART -- KARING HEARTS CARDIOLOGY

Give information for the last three (3) years for which complete data are available for the facility or agency (SEE NOTE)
The fiscal year begins in January.

		Year 2011	Year 2012	Year 2013
	Patient Encounters	2314	6512	9302
A.	Utilization Data			
B.	Revenue from Services to Patients			
1.	Inpatient Services	$		
2.	Outpatient Services	1,705,926	4,816,252	6,206,680
3.	Emergency Services			
4.	Other Operating Revenue			
	(Specify) See notes page			
	Gross Operating Revenue	$ 1,705,926	$ 4,816,252	$ 6,206,680
C.	Deductions for Operating Revenue			
1.	Contractual Adjustments	$ 1,125,911	3,082,401	3,910,208
2.	Provision for Charity Care (5%)	85,296	240,813	310,334
3.	Provisions for Bad Debt	99,133	112,400	121,973
	Total Deductions	$ 1,310,340	$ 3,435,614	$ 4,342,515
NET OPERATING REVENUE		$ 395,586	$ 1,380,638	$ 1,864,165
D.	Operating Expenses			
1.	Salaries and Wages	$ 190,960	558,824	624,888
2.	Physicians Salaries and Wages	130,363	323,561	422,736
3.	Supplies	2,438	12,360	35,302
4.	Taxes	400	975	3,992
5.	Depreciation	12,143	77,965	104,393
6.	Rent	22,464	37,021	57,175
7.	Interest, other than Capital	0	0	0
8.	Management Fees	0	0	0
	a. Fees to Affiliates	0	0	0
	b. Fees to Non-Affiliates	0	0	0
9.	Other Expenses (Specify) See notes page	129,959	314,422	448,842
	Total Operating Expenses	$ 488,727	1,325,128	1,697,328
E.	Other Revenue (Expenses) -- Net (Specify)	$	$	$
NET OPERATING INCOME (LOSS)		$ (93,141)	$ 55,510	$ 166,837
F.	Capital Expenditures			
1.	Retirement of Principal	$ 0	$ 26,539	$ 54,830
2.	Interest	8,034	17,130	15,510
	Total Capital Expenditures	$ 8,034	$ 43,669	$ 70,340
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES		$ (101,175)	$ 11,841	$ 96,497

Note: CY2011 is a partial year, in which Dr. Schoondyke left a local cardiology group to set up an independent practice.

HISTORIC DATA CHART
NOTES TO OTHER EXPENSES (LINE D9)

	CY2011	CY2012	CY2013
Employee benefits	15,163	28,360	36,844
General office supplies	31,723	74,362	75,119
Leasehold Im/Abandonmnt	0	28,253	0
Charitable Donations	5,145	15,365	17,389
Advertising Bus dev	44,763	22,954	14,942
Contracted Services	2,919	7,380	7,994
Meals and Entertainment	604	6,245	20,502
Utilities	6,739	36,989	69,012
Service repairs	1,090	10,391	15,281
Insurance/Licensing/Accreditation	7,245	18,356	28,998
Billing fee	10,721	39,788	27,524
Accounting	3,080	7,495	15,336
Legal	767	18,484	0
Owner Draws	0	0	119,900
TOTAL	129,959	314,422	448,841

PROJECTED DATA CHART– KARING HEARTS CARDIOLOGY CARDIAC PET SERVICE

Give information for the two (2) years following the completion of this proposal.
The fiscal year begins in January.

			CY 2015	CY 2016
		PATIENTS	678	745
A.	Utilization Data	PROCEDURES	678	745
B.	Revenue from Services to Patients			
	1. Inpatient Services		$	$
	2. Outpatient Services		2,063,832	2,155,285
	3. Emergency Services			
	4. Other Operating Revenue (Specify)	See notes page		
		Gross Operating Revenue	$ 2,063,832	$ 2,155,285
C.	Deductions for Operating Revenue			
	1. Contractual Adjustments		$ 866,809	$ 905,220
	2. Provision for Charity Care (3%)		61,915	64,659
	3. Provisions for Bad Debt (1%)		20,638	21,553
		Total Deductions	$ 949,363	$ 991,431
NET OPERATING REVENUE			$ 1,114,469	$ 1,163,854
D.	Operating Expenses			
	1. Salaries and Wages		$ 107,500	$ 110,725
	2. Physicians Salaries and Wages		225,000	231,750
	3. Supplies		425,106	467,115
	4. Taxes		3,343	3,492
	5. Depreciation		6,667	6,667
	6. Rent		10,860	10,860
	7. Interest, other than Capital		0	0
	8. Management Fees			
	a. Fees to Affiliates		0	0
	b. Fees to Non-Affiliates		0	0
	9. Other Expenses (Specify)	See notes page	269,583	275,655
	Dues, Utilities, Insurance, and Prop Taxes.			
		Total Operating Expenses	$ 1,048,059	$ 1,106,263
E.	Other Revenue (Expenses) -- Net (Specify)		$	$
NET OPERATING INCOME (LOSS)			$ 66,410	$ 57,591
F.	Capital Expenditures			
	1. Retirement of Principal		$ 11,685	$ 12,245
	2. Interest		5,857	5,297
		Total Capital Expenditures	$ 17,542	$ 17,542
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES			$ 48,868	$ 40,049

SUPPLEMENTAL- # 1
November 26, 2013
12:40pm

PROJECTED DATA CHART
NOTES TO OTHER EXPENSES (LINE D9)

		CY2014		CY2015
Employee benefits		10,750		11,073
Overhead salaries		35,816		36,890
General office supplies		3,348		3,438
Advertising Bus dev		2,500		2,500
Meals and Entertainment		1,755		1,808
Utilities		16,054		16,535
Accreditation Fee		3,300		0
Service repairs		18,400		24,400
Insurance and Lice		2,495		2,569
Equip Lease		144,000		144,000
Billing fee	2.5%	27,862		29,096
Accounting		1,303		1,346
		2,000		2,000
	TOTAL	269,583		275,655

Overhead Salaries	
mngmnt	25000
Med records	4992
Admin coord	5824

	Supples (D3) Summary	
	678	745
N-13 = $380	$257,640	$283,100
Lexi = $232	$157,296	$172,840
General = $15	$10,170	$11,175
	$425,106	$467,115

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

Table Nine: Average Charges, Deductions, and Net Charges Karing Hearts Cardiology Cardiac PET Service		
	CY2015	**CY2016**
Procedures & Patients	678	745
Average Gross Charge Per Procedure & Patient	$3,044	$2,893
Average Deduction Per Procedure & Patient	$1,400	$1,331
Average Net Charge (Net Operating Revenue) Per Procedure & Patient	$1,644	$1,562
Average Net Operating Income Per Procedure & Patient, After Capital Expenditures	$103	$77

C(II).6.A. PLEASE PROVIDE THE CURRENT AND PROPOSED CHARGE SCHEDULES FOR THE PROPOSAL. DISCUSS ANY ADJUSTMENT TO CURRENT CHARGES THAT WILL RESULT FROM THE IMPLEMENTATION OF THE PROPOSAL. ADDITIONALLY, DESCRIBE THE ANTICIPATED REVENUE FROM THE PROPOSED PROJECT AND THE IMPACT ON EXISTING PATIENT CHARGES.

For proposed charges, please see C(II).6.B below. Because this project is for a physician practice service, with a positive operating margin, there are no other types of charges that could be impacted by the project. The Projected Data Chart shows that the applicant will be maintaining approximately the same net operating revenue per procedure (amount actually received from payors after deductions) as the prior owner experienced. See Table Ten in response C(II).6.B below.

C(II).6.B. COMPARE THE PROPOSED CHARGES TO THOSE OF SIMILAR FACILITIES IN THE SERVICE AREA/ADJOINING SERVICE AREAS, OR TO PROPOSED CHARGES OF PROJECTS RECENTLY APPROVED BY THE HSDA. IF APPLICABLE, COMPARE THE PROJECTED CHARGES OF THE PROJECT TO THE CURRENT MEDICARE ALLOWABLE FEE SCHEDULE BY COMMON PROCEDURE TERMINOLOGY (CPT) CODE(S).

Table Ten below compares this project's projected charges to the recently approved projected charges of Wellmont Cardiac Services' cardiac PET service in Kingsport, and Molecular Imaging Alliance's approved CON application to relocate its Cardiac PET ODC to Johnson City.

The projected average gross charge for this ODC in 2014 in Johnson City is projected to be higher than at the Gray location in CY2012. However, the ODC's projected average net operating revenue (receipts), which is its impact on payors, will be lower.

Table Ten: Comparative Gross Charges Per Cardiac PET Scan	
Provider	**Average Gross / Net Revenue**
Molecular Imaging Alliance, Gray (Soteria)	Actual 2012: $4,791 / $1,855
Wellmont Cardiology Services at Kingsport	Proposed, CY2014: $3,678 / $1,140
Molecular Imaging Alliance, Johnson City	Proposed, CY2014: $3,133 / $1,675
Karing Hearts Cardiology, Johnson City	Proposed, CY2015: $3,044 / $1,644

Source: HSDA records; Applicant's Projected Data Chart, this application.

The following page contains Table Eleven, a chart showing the most frequent procedures to be performed, with their current Medicare reimbursement, and their projected Years One and Two utilization and average gross charges.

Table Eleven: Karing Hearts Cardiology Cardiac PET Service Charge Data for Most Frequently Performed Procedures

SERVICE CARDIAC PET

CPT	Descriptor	Current Medicare Allowable	Average Gross Charge			Utilization		
			Current	Year 1	Year 2	Current	Year 1	Year 2
78492	PET MYOCARD PRF MUL RST/STRS	$1,033	3,205.00	3,044.75	2,892.51	na	668	734
78459	PET MYOCARDIAL IMAGING	$1,016	3,205.00	3,044.75	2,892.51	na	10	11
A9526	NITROGEN N-13 AMMONIA	*Invoice Total	380.00	380.00	380.00	na	678	745
J2785	LEXISCAN 0.1 MG	$54	100.00	100.00	100.00	na	678	745

Source: Practice Management

C(II).7. DISCUSS HOW PROJECTED UTILIZATION RATES WILL BE SUFFICIENT TO MAINTAIN COST-EFFECTIVENESS.

The service is projected to operate with a positive cash flow and a rapid annual increase of utilization; its continued increases in utilization will be sufficient to ensure its long-term viability.

C(II).8. DISCUSS HOW FINANCIAL VIABILITY WILL BE ENSURED WITHIN TWO YEARS; AND DEMONSTRATE THE AVAILABILITY OF SUFFICIENT CASH FLOW UNTIL FINANCIAL VIABILITY IS MAINTAINED.

The applicant is an established medical practice with active reimbursement income, so addition of the service should not cause any cash flow issues.

C(II).9. DISCUSS THE PROJECT'S PARTICIPATION IN STATE AND FEDERAL REVENUE PROGRAMS, INCLUDING A DESCRIPTION OF THE EXTENT TO WHICH MEDICARE, TENNCARE/MEDICAID, AND MEDICALLY INDIGENT PATIENTS WILL BE SERVED BY THE PROJECT. IN ADDITION, REPORT THE ESTIMATED DOLLAR AMOUNT OF REVENUE AND PERCENTAGE OF TOTAL PROJECT REVENUE ANTICIPATED FROM EACH OF TENNCARE, MEDICARE, OR OTHER STATE AND FEDERAL SOURCES FOR THE PROPOSAL'S FIRST YEAR OF OPERATION.

The applicant participates in Medicare and contracts with all area TennCare MCO's and Virginia Medicaid. Its projected payor mix for this proposed new nuclear medicine service is 60% Medicare and 6% TennCare/Medicaid. Indigent care is projected at 3% of gross revenues under the new ownership.

Table Twelve: Medicare and TennCare/Medicaid Revenues, Year One		
	Medicare	**TennCare/Medicaid**
Gross Revenue	$1,238,299	$123,830
Percent of Gross Revenue	60%	6%

C(II).10. PROVIDE COPIES OF THE BALANCE SHEET AND INCOME STATEMENT FROM THE MOST RECENT REPORTING PERIOD OF THE INSTITUTION, AND THE MOST RECENT AUDITED FINANCIAL STATEMENTS WITH ACCOMPANYING NOTES, IF APPLICABLE. FOR NEW PROJECTS, PROVIDE FINANCIAL INFORMATION FOR THE CORPORATION, PARTNERSHIP, OR PRINCIPAL PARTIES INVOLVED WITH THE PROJECT. COPIES MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND LABELED AS ATTACHMENT C, ECONOMIC FEASIBILITY--10.

These are provided as Attachment C, Economic Feasibility--10.

C(II)11. DESCRIBE ALL ALTERNATIVES TO THIS PROJECT WHICH WERE CONSIDERED AND DISCUSS THE ADVANTAGES AND DISADVANTAGES OF EACH ALTERNATIVE, INCLUDING BUT NOT LIMITED TO:

A. A DISCUSSSION REGARDING THE AVAILABILITY OF LESS COSTLY, MORE EFFECTIVE, AND/OR MORE EFFICIENT ALTERNATIVE METHODS OF PROVIDING THE BENEFITS INTENDED BY THE PROPOSAL. IF DEVELOPMENT OF SUCH ALTERNATIVES IS NOT PRACTICABLE, THE APPLICANT SHOULD JUSTIFY WHY NOT, INCLUDING REASONS AS TO WHY THEY WERE REJECTED.

B. THE APPLICANT SHOULD DOCUMENT THAT CONSIDERATION HAS BEEN GIVEN TO ALTERNATIVES TO NEW CONSTRUCTION, E.G., MODERNIZATION OR SHARING ARRANGEMENTS. IT SHOULD BE DOCUMENTED THAT SUPERIOR ALTERNATIVES HAVE BEEN IMPLEMENTED TO THE MAXIMUM EXTENT PRACTICABLE.

A. The applicant knows of no less costly, more effective, or more efficient way to ensure the continuation of this service for patients of its service area. The ODC that was approved to relocate to this same building has announced its intention to close before doing so. Its cardiac PET equipment is vital to the quality of care for patients of this practice. Karing Hearts Cardiology is willing to take over the equipment lease and to offer the service in its practice office. The capital cost to move it into a new location under new ownership is minimal. Relocation of the service, into the heart of the largest medical services provider community in Washington County, provides better access for patients whose physicians would like them to receive cardiac PET scans. By making the service more accessible, the project will increase the use of cardiac PET scanning relative to SPECT studies, with all the attendant cost savings and diagnostic improvements that have been discussed earlier.

B. The project relies entirely on renovation and requires no new construction.

C(III).1. LIST ALL EXISTING HEALTH CARE PROVIDERS (I.E., HOSPITALS, NURSING HOMES, HOME CARE ORGANIZATIONS, ETC.) MANAGED CARE ORGANIZATIONS, ALLIANCES, AND/OR NETWORKS WITH WHICH THE APPLICANT CURRENTLY HAS OR PLANS TO HAVE CONTRACTUAL AND/OR WORKING RELATIONSHIPS, E.G., TRANSFER AGREEMENTS, CONTRACTUAL AGREEMENTS FOR HEALTH SERVICES.

If approved for the relocation, Karing Hearts Cardiology will seek a transfer agreement with MSHA's Johnson City Medical Center, which is less than one mile away on the same street as the practice.

C(III).2. DESCRIBE THE POSITIVE AND/OR NEGATIVE EFFECTS OF THE PROPOSAL ON THE HEALTH CARE SYSTEM. PLEASE BE SURE TO DISCUSS ANY INSTANCES OF DUPLICATION OR COMPETITION ARISING FROM YOUR PROPOSAL, INCLUDING A DESCRIPTION OF THE EFFECT THE PROPOSAL WILL HAVE ON THE UTILIZATION RATES OF EXISTING PROVIDERS IN THE SERVICE AREA OF THE PROJECT.

Because the applicant is proposing to acquire and operate its primary service area's only remaining cardiac PET scanner, and because this is a simple relocation within the same county and service area, it does not seem possible that the project would create any competitive issues, or would duplicate existing technology. The only other such unit in the region will be the cardiac PET at Wellmont Cardiology Services in the adjoining county. That provider has already declared, and documented to the HAS in its approved CN1304-013, that its unit will be fully utilized by its own internal patients who will be switched from using SPECT testing to using cardiac PET testing. So the unit being proposed in this project will not be competing with any other cardiac PET in the region. And, because no conventional PET unit in the service area seems to have both the capability and the capacity to provide additional cardiac PET scans, it seems unlikely that the relocation and change of ownership of the Gray cardiac PET system could create any competitive issues with any conventional PET in the area.

C(III).3. PROVIDE THE CURRENT AND/OR ANTICIPATED STAFFING PATTERN FOR ALL EMPLOYEES PROVIDING PATIENT CARE FOR THE PROJECT. THIS CAN BE REPORTED USING FTE'S FOR THESE POSITIONS. IN ADDITION, PLEASE COMPARE THE CLINICAL STAFF SALARIES IN THE PROPOSAL TO PREVAILING WAGE PATTERNS IN THE SERVICE AREA AS PUBLISHED BY THE TENNESSEE DEPARTMENT OF LABOR & WORKFORCE DEVELOPMENT AND/OR OTHER DOCUMENTED SOURCES.

Please see the following page for Table Fourteen, projected FTE's and salary ranges.

The Department of Labor and Workforce Development website indicates the following annual salary information in the area, for clinical employees of the type to be employed in this project:

Table Thirteen: TDOL Surveyed Average Salaries for the Service Area				
Position	**Entry Level**	**Mean**	**Median**	**Experienced**
RN	$40,450	$57,870	$56,050	$66,590
Nuclear Med. Tech*	$54,290	$60,050	$59,210	$62,940

**This position was not surveyed in the Johnson City region. Data here is for Kingsport area, the closest comparable market.*

Table Fourteen: Karing Hearts Cardiology, PLLC--Cardiac PET Service Staffing Requirements				
Position Type (RN, etc.)	Current FTE's	Year One FTE's	Year Two FTE's	Salary Range (Annual)
Registered Nurse	0	0.5	0.5	$40k - $50k/yr
Nuclear Medicine Technologist	0	1	1	$65k - $75k/yr
Reception	0	0.5	0.5	$25k - $30k/yr
Total FTE's				

C(III).4. DISCUSS THE AVAILABILITY OF AND ACCESSIBILITY TO HUMAN RESOURCES REQUIRED BY THE PROPOSAL, INCLUDING ADEQUATE PROFESSIONAL STAFF, AS PER THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, AND/OR THE DIVISION OF MENTAL RETARDATION SERVICES LICENSING REQUIREMENTS.

The project will obtain its nuclear medicine tech from the ODC that is closing this service. The RN will be shared with the practice.

C(III).5. VERIFY THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSING CERTIFICATION AS REQUIRED BY THE STATE OF TENNESSEE FOR MEDICAL/CLINICAL STAFF. THESE INCLUDE, WITHOUT LIMITATION, REGULATIONS CONCERNING PHYSICIAN SUPERVISION, CREDENTIALING, ADMISSIONS PRIVILEGES, QUALITY ASSURANCE POLICIES AND PROGRAMS, UTILIZATION REVIEW PPOLICIES AND PROGRAMS, RECORD KEEPING, AND STAFF EDUCATION.

The applicant is familiar with the licensing requirements for a nuclear medicine tech, a Registered Nurse, and the licensing requirements for handling radioactive isotopes and materials.

C(III).6. DISCUSS YOUR HEALTH CARE INSTITUTION'S PARTICIPATION IN THE TRAINING OF STUDENTS IN THE AREAS OF MEDICINE, NURSING, SOCIAL WORK, ETC. (I.E., INTERNSHIPS, RESIDENCIES, ETC.).

This small practice is not currently affiliated with any health professional training programs at the present time. However, the applicant would be pleased to consider offering a clinical rotation for cardiac PET studies, if it acquires this new service and if a local training program would be interested in such an addition.

C(III).7(a). PLEASE VERIFY, AS APPLICABLE, THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSURE REQUIREMENTS OF THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, THE DIVISION OF MENTAL RETARDATION SERVICES, AND/OR ANY APPLICABLE MEDICARE REQUIREMENTS.

The applicant so verifies. No facility license is required from TDH. The Department of Environment and Conservation, however, already licenses this practice to handle radioactive materials for nuclear medicine studies.

C(III).7(b). PROVIDE THE NAME OF THE ENTITY FROM WHICH THE APPLICANT HAS RECEIVED OR WILL RECEIVE LICENSURE, CERTIFICATION, AND/OR ACCREDITATION

LICENSURE:	Radioactive Materials License from Tennessee Department of Environment and Conservation
CERTIFICATION:	Medicare Certification from CMS TennCare Certification from TDH
ACCREDITATION:	Intersocietal Commission on Accreditation

C(III).7(c). IF AN EXISTING INSTITUTION, PLEASE DESCRIBE THE CURRENT STANDING WITH ANY LICENSING, CERTIFYING, OR ACCREDITING AGENCY OR AGENCY.

The applicant physician practice is currently certified for participation in Medicare and Medicaid/TennCare, and licensed to handle radioactive materials. It will seek accreditation for its PET service from Intersocietal Commission on Accreditation.

C(III).7(d). FOR EXISTING LICENSED PROVIDERS, DOCUMENT THAT ALL DEFICIENCIES (IF ANY) CITED IN THE LAST LICENSURE CERTIFICATION AND INSPECTION HAVE BEEN ADDRESSED THROUGH AN APPROVED PLAN OF CORRECTION. PLEASE INCLUDE A COPY OF THE MOST RECENT LICENSURE/CERTIFICATION INSPECTION WITH AN APPROVED PLAN OF CORRECTION.

Not applicable to a private medical practice.

C(III)8. DOCUMENT AND EXPLAIN ANY FINAL ORDERS OR JUDGMENTS ENTERED IN ANY STATE OR COUNTRY BY A LICENSING AGENCY OR COURT AGAINST PROFESSIONAL LICENSES HELD BY THE APPLICANT OR ANY ENTITIES OR PERSONS WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE APPLICANT. SUCH INFORMATION IS TO BE PROVIDED FOR LICENSES REGARDLESS OF WHETHER SUCH LICENSE IS CURRENTLY HELD.

None.

C(III)9. IDENTIFY AND EXPLAIN ANY FINAL CIVIL OR CRIMINAL JUDGMENTS FOR FRAUD OR THEFT AGAINST ANY PERSON OR ENTITY WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE PROJECT.

None.

C(III)10. IF THE PROPOSAL IS APPROVED, PLEASE DISCUSS WHETHER THE APPLICANT WILL PROVIDE THE THSDA AND/OR THE REVIEWING AGENCY INFORMATION CONCERNING THE NUMBER OF PATIENTS TREATED, THE NUMBER AND TYPE OF PROCEDURES PERFORMED, AND OTHER DATA AS REQUIRED.

Yes. The applicant will provide the requested data consistent with Federal HIPAA requirements.

PROOF OF PUBLICATION

Attached.

DEVELOPMENT SCHEDULE

1. PLEASE COMPLETE THE PROJECT COMPLETION FORECAST CHART ON THE NEXT PAGE. IF THE PROJECT WILL BE COMPLETED IN MULTIPLE PHASES, PLEASE IDENTIFY THE ANTICIPATED COMPLETION DATE FOR EACH PHASE.

The Project Completion Forecast Chart is provided after this page.

2. IF THE RESPONSE TO THE PRECEDING QUESTION INDICATES THAT THE APPLICANT DOES NOT ANTICIPATE COMPLETING THE PROJECT WITHIN THE PERIOD OF VALIDITY AS DEFINED IN THE PRECEDING PARAGRAPH, PLEASE STATE BELOW ANY REQUEST FOR AN EXTENDED SCHEDULE AND DOCUMENT THE "GOOD CAUSE" FOR SUCH AN EXTENSION.

Not applicable. The applicant anticipates completing the project within the period of validity.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision Date, as published in Rule 68-11-1609(c):

February 26, 2014

Assuming the CON decision becomes the final Agency action on that date, indicate the number of days from the above agency decision date to each phase of the completion forecast.

PHASE	DAYS REQUIRED	Anticipated Date (MONTH /YEAR)
1. Architectural & engineering contract signed	2	3-1-14
2. Construction documents approved by TDH	na	na
3. Construction contract signed	17	3-15-14
4. Building permit secured	20	3-18-14
5. Site preparation completed	na	na
6. Building construction commenced	32	4-1-14
7. Construction 40% complete	92	6-1-14
8. Construction 80% complete	152	8-1-14
9. Construction 100% complete	212	10-1-14
10. * Issuance of license (if required)	na	na
11. *Initiation of service	227	10-15-14
12. Final architectural certification of payment	287	12-15-14
13. Final Project Report Form (HF0055)	317	1-14-15

*** For projects that do NOT involve construction or renovation: please complete items 10-11 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

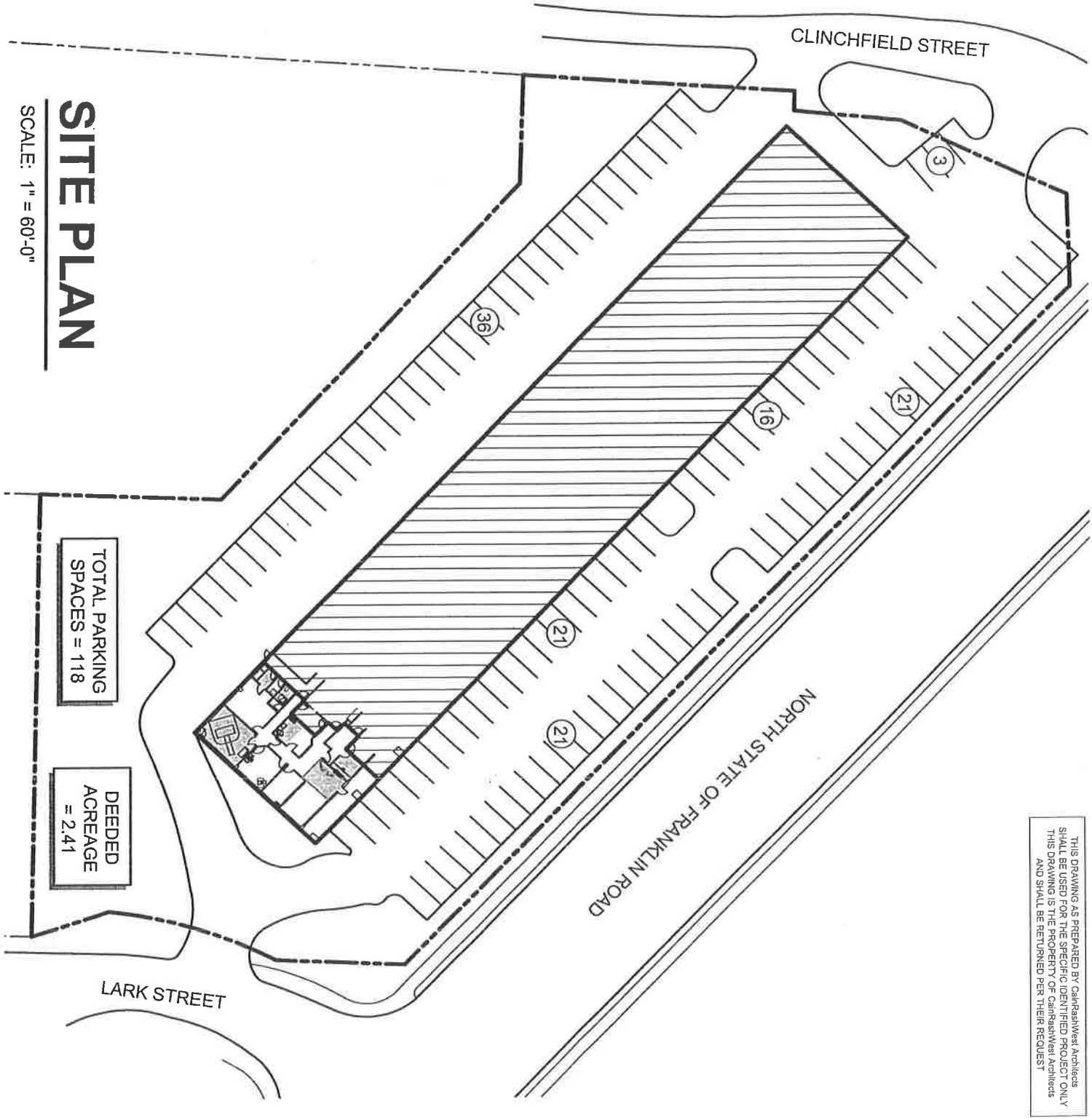
INDEX OF ATTACHMENTS

A.4	Ownership--Legal Entity and Organization Chart (if applicable)
A.6	Site Control and Documentation of Building Market Value
B.II.E.1.	Fixed Major Medical Equipment--FDA Approval Documentation
B.II.E.3	Major Medical Equipment-- Draft Lease; Market Value
B.III.	Plot Plan
B.IV.	Floor Plan
C, Need--1A	Documentation of Project-Specific Criteria 1. Qualifications of Dr. Jeffrey Schoondyke 2. Qualifications of Dr. Melanie Davidson 3. Emergency Response Protocols 4. Medical Necessity Protocols 5. Medical Director Specifications
C, Need--1.A.3.	Letters of Intent 1. ODC's Letter of Intent to Surrender CN1304-014 and to Cease Operation 2. Letter of Intent from Radiopharmaceutical Vendor
C, Need--3	Service Area Maps
C, Economic Feasibility--1	Documentation of Construction Cost Estimate
C, Economic Feasibility--2	Documentation of Availability of Funding
C, Economic Feasibility--10	Financial Statements of Applicant
Miscellaneous Information	1. TennCare Statistics 2. PSA Demographic Data Source 3. Articles on Cardiac PET Technology 4. Medically Underserved Areas in the Project Service Area
Support Letters	

B.III.--Plot Plan

SITE PLAN

SCALE: 1" = 60'-0"



Cain Rash West Architects
Architectural Services
130 Regional Park Dr.
Kingsport, TN 37660
Phn (423) 349-7760
Fax (423) 349-7413
www.grcinc.com

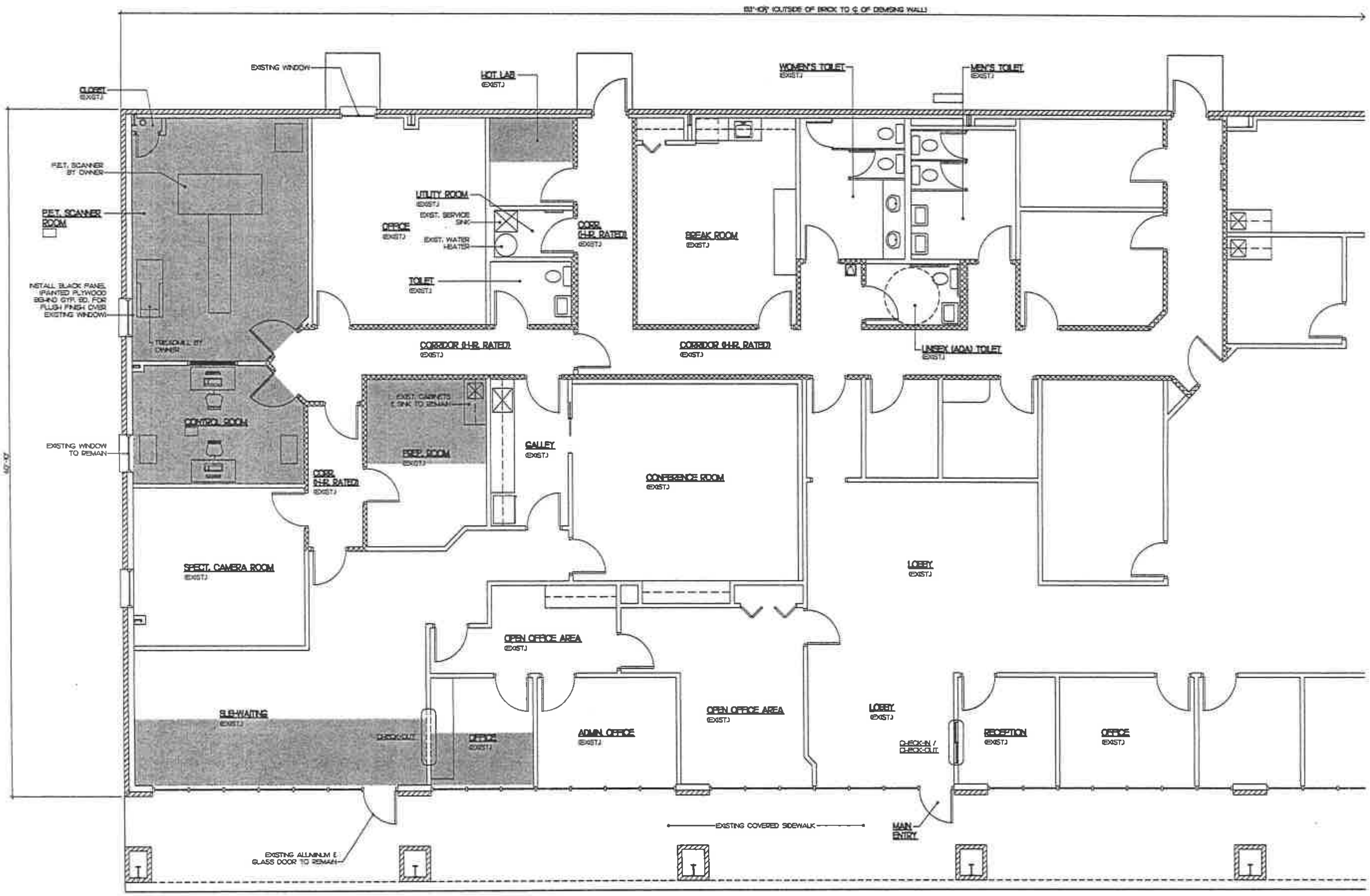
MOLECULAR IMAGING CENTER
FOR:
LIFESCAN OF TENNESSEE

701 N. STATE OF FRANKLIN ROAD, SUITE 1
JOHNSON CITY, TENNESSEE

issued	04/11/2013
drawn by	BVH
project no.	00-00
drawing name	SITE PLAN

C-1

B.IV.--Floor Plan



WALL LEGEND:

- NEW WALL CONSTRUCTION
- EXISTING WALL TO REMAIN
- EXISTING - TO BE REMOVED
- EXISTING 1-HOUR FIRE-RATED WALLS
- WALLS TO BE CONVERTED TO OR BUILT AS 1-HOUR FIRE-RATED WALLS

REFERENCE FLOOR PLAN

SCALE: 1/8"=1'-0"

MITCH COX
CONSTRUCTION, INC.
801 Sunset Drive, Suite D-1
Johnson City, TN 37604
PHONE 423.282.6582
FAX 423.282.5903
mitchcox.com

PROJECT: RENOVATIONS FOR P.E.T. SCANNER AT:

KARING HEARTS CARDIOLOGY

SUITE #2

701 STATE OF FRANKLIN ROAD JOHNSON CITY, TN

DATE: NOV. 13, '13

JOB NO.

REVISIONS: NOV. 14, '13

SHEET DESCRIPTION

REFERENCE FLOOR PLAN

SHEET NUMBER

A-1

KARING HEARTS

C, Need--1.A
Documentation of Project-Specific Criteria

Medical Necessity Policy – Cardiac PET Protocol

The following protocol is prepared to insure that ordered Cardiac PET procedures are medically necessary.

Purpose:
To provide quality assurance with respect to medical necessity for cardiac PET examinations.

Protocol:

1. All requests for cardiac PET procedures must be in compliance with current Appropriate Use Criteria for PET studies published jointly, and periodically updated, by the American College of Cardiology and the American Society of Nuclear Cardiology.
2. No cardiac PET procedure will be completed without a documented request from a Karing Hearts Cardiology provider.
3. If the Clinical Director of the PET service has any concerns about the appropriateness of a PET study that has been requested, he or she shall contact the Medical Director for Cardiac PET, who will, if appropriate, contact the referring physician for discussion and confirmation of necessity, before performing the requested procedure.
4. Data will be kept and analyzed on a semiannual basis for each ordering provider and timely feedback given to all providers so that any concerns about PET utilization can be addressed.

701 N State of Franklin, Ste 2

www.karingheartscardiology.com * 423-926-4468 * fax 423-928-4838

Cardiac PET Medical Director – Job Description

Medical Director must be a licensed physician and be an authorized user of radioisotopes according to NRC or state regulatory agency regulations. The medical Director must also be an authorized user of nuclear medicine therapies.

Cardiac PET Medical Director Criteria:

a. Board certified in cardiology
b. Minimum of 500 independently interpreted PET cases within the previous 2 years

Cardiac PET Medical Director Responsibilities:

Responsible for all nuclear medicine services provided including quality control (QC), radiation safety, quality of care and appropriateness of care. These responsibilities include but are not limited to:

a. The Medical Director will assume compliance with all policies/procedures/protocols and will review and update all manuals periodically as necessary (minimum every year) or as new policies are introduced. This review must be documented via signature (or initials) and date on the reviewed document or manual.
b. Active oversight of radiation safety within the facility.
c. The Medical Director must provide the final interpretation/report of some nuclear medicine procedures for the facility.
d. Medical oversight, supervision and direction of the operation
e. Responsible for the medical administrative management of Cardiac PET testing while optimizing clinical outcomes and patient satisfaction
f. Active participation in budget management
g. Responsible for ensuring high quality interpretive services

h. Responsible for the management of procedure reports and data storage systems that provide for timely results to providers as well as access to various points of care in the health system

Cardiac PET Medical Director Continuing Medical Education (CME) Requirements:

a. The Medical Director must obtain at least 15 hours of AMA category 1 CME credits, relevant to nuclear medicine, every three years
Documentation of CME credits must be kept on file and available for inspection

Karing Hearts Cardiology

A proud supporter of Kim's Heart Foundation

CODE BLUE POLICY

PURPOSE:

To provide employees of Karing Heart's Cardiology with a plan of action in the even a patient suffers cardiopulmonary arrest. Karing Heart's Cardiology will post this CODE BLUE procedure in the following areas:

A. PET/Nuclear Scanner room(s)
B. ECHO/Vascular room(s)
C. Technologist Control Room(s)
D. Patient Foyer

PROCEDURE:

A. The onsite supervising physician will be responsible for conducting the code and direct all CPR and resuscitation attempts.
B. In the even there is not a physician onsite, the ACLS trained nurse or technologist will assume the responsibility of supervising the care of the patient.
    i. Assess the patient following the American Heart Association guidelines:
        a. Check for consciousness. If unconscious call for help, the Code Cart and make sure that 911 has been called.
        b. Check for breathing. Initiate/support oxygenation with the ambu and oxygen tank as indicated.
        c. Attach AED and follow prompts.
        d. CPR will be performed when indicated by personnel trained in AHA basic life support.
C. Staff not directly involved in caring for the patient during the emergency will maintain a calm, supportive atmosphere for any friends, family or other patients present in the facility during the emergency.
    a. This person will also direct EMS to the back emergency door upon arrival.
D. Continue to support the patient per AHA guidelines until EMS arrives to assume care.

   a. The supervising nurse or technologist will provide paramedics with all pertinent medical information along with a detailed report of any contrast or medications given to the patient during their test and emergency care.
   b. The patient will be transported by EMS to the nearest emergency medical facility, which will be Johnson City Medical Center, located at 400 North State of Franklin Road, Johnson City, TN.

E. The nurse or technologist will notify the appropriate individuals of the emergency and patient disposition.
   a. The patient's emergency contact if not present at the time of the occurrence
   b. The patient's attending/referring physician
   c. Karing Heart's facility manager
F. The nurse or technologist will fully document the incident and all interventions in the patient's chart.
G. The facility manager will monitor the patient's progress.
   a. Contacting the physician treating the patient at the hospital where the patient is taken
   b. Following up with the patient/and or family members
H. The facility manager will complete the Karing Heart's Incident and Accident report.

REFERENCES:

JACHO standard
American Heart Association
ICANL Administrative protocol
IDTF policy and procedure manual

PREPARED BY:_____ **DATE:**_____

REVIEWED BY:_____ **DATE:**_____

APPROVED BY:_____ **DATE:**_____

Jeffrey W. Schoondyke MD, MPH, FACC, CCDS
212 Highland Gate Dr.
Johnson City, TN 37601
(H) 423-753-6655
J3schoondyke@yahoo.com

Biographical Data

Birthplace: Rock Island, Illinois (12/31/1968)
Marital Status: Married
Spouse Name: Jennifer Schoondyke
Children: Jeffrey, Age 15
Kathryn, Age 13
Kari Elizabeth, 7 months

Education/Employment History	Degree	Dates of Attendance
• Northern Arizona University Flagstaff, AZ	BS	8/87-5/92
• University of Oklahoma Oklahoma City, OK	MPH	8/92-5/95
• St. George's University School of Medicine Grenada, West Indies	MD	8/95-5/99
• East Tennessee State University Department of Internal Medicine Residency Program Johnson City, TN 37614		7/99-6/02
• Cardiology Fellowship East Tennessee State University Department of Cardiology Johnson City, TN 37614		7/02-6/05
• Johnson City Emergency Physicians- Contract ER Physician Johnson City Medical Center VAMC Mountain Home Tennessee Johnson County Medical Center		7/02-6/05
• Bristol Consultants, PC Bristol Regional Medical Center Bristol, TN		2/04-6/05
• Halifax Heart Center, PC Boston, VA Cardiologist		7/05-5/06
• Mountain States Medical Group Formerly Heart & Vascular Johnson City, TN Cardiologist		6/06-2/11

- Karing Hearts Cardiology, PLLC — 3/2011-Present
  Johnson City, TN
  Cardiologist

Academic Appointments — 6/06-present

- East Tennessee State University
  Associate Professor of Medicine/Cardiology
  James H. Quillen College of Medicine Johnson City, TN

Licensure and Boards	**Date of Examination**
Board Certified Internal Medicine	8/2002
Board Certified Cardiovascular Disease	11/2005
Heart Rhythm/NASPE Certified- CCDS	9/2007
Tennessee Medical License #36563	
Virginia Medical License #0101237133	
North Carolina Medical License #2005-01437	
Current DEA Registration #BS7825790	

Professional Memberships

- American College of Cardiology
- American Board of Internal Medicine
- Heart Rhythm Society
- Tennessee Medical Society

Cardiovascular Skill Set

- Diagnostic Left and Right Cardiac Catheterization
- Trans-Esophageal Echocardiography
- Trans-Thoracic Echocardiography
- SPECT Perfusion Imaging Interpretation
- Cardiac PET Scanning
- DC Cardioversion
- Permanent Pacemaker Insertion
- Bi-Ventricular ICD/Pacemaker Insertion
- ICD Insertion
- IABP Insertion
- Pericardiocentesis

Presentations

- **Schoondyke Jeffrey W., MD, MPH**; Fitzpatrick Oney, D., Ph.D. Sexual Attitudes and Behaviors for a New Generation: Are They Really Changing? Slide Presentation at the Rocky Mountain Psychological Association Conference.
  Denver, Colorado. 1991.

- Mohan Rajesh, M.D.; Kelly Jim, Ph.D.; Ponder Michael, M.D.; **Schoondyke Jeffrey W., M.D., MPH**; Douglas John E., M.D. Fosinopril Induced Hepatotoxicity- Review of the literature and description of the first case in humans. 2001 International Experimental Biology Meeting. April 4, 2001, Orlando, Fl.

- **Schoondyke Jeffrey W., MD, MPH**; Mohan Rajesh, MD; Appakondu Sirinivasa, MD; Sandhu Dalpinder, MD; Downs Chris, MD; Bala Chidambaram, M.D.; Ponder Michael, MD, FACC. Elevated Troponin-I in a Patient With Acute Pulmonary Embolism Without Evidence of Coronary Artery Disease - A review of the literature and description of a case presenting with chest pain, acute onset shortness of breath and hypoxia. 2001 International Experimental Biology Meeting, April 4, 2001. Orlando, Fl.

- **Schoondyke Jeffrey W., MD, MPH;** Baha Shabaneah, MD; Jack Whitaker, MD. Papillary Fibroelastoma of the left ventricle. Southern Medical Association National Meeting. November, 2002.

- **Schoondyke, Jeffrey W., MD, MPH**. 7th Annual Nurse Practitioner/Physician Assistant Conference for Primary Care. CHF Lecture Incorporating the New ACC Guidelines. April 1, 2003.

- **Schoondyke, Jeffrey, W. MD, MPH**. CHF Update. *Medical College of Georgia* Grand Rounds. May 2003.

- **Schoondyke, Jeffrey W. MD, MPH, FACC** Mended Hearts Monthly Meeting 3-09.

- **Schoondyke, Jeffrey W. MD, MPH, FACC.** Keynote Speaker, Mended Little Hearts Inaugural Chapter Meeting. Niswonger Children's Hospital, April 23, 2009.

- **Schoondyke, Jeffrey W. MD, MPH, FACC**. ETSU College of Medicine Annual Cardiovascular CME New Horizons Symposium. Post MI Care: An Update for Primary Care Physicians. May 2, 2009.

- **Schoondyke, Jeffrey W. MD, MPH, FACC, CCDS**. ETSU College of Medicine Annual Cardiovascular CME New Horizons Symposium. Progress in Stress Testing and Nuclear Imaging. January 25, 2013.

Research & Publications

- **Schoondyke Jeffrey W., MD, MPH**; Fitzpatrick Oney, D., Ph.D. Sexual Attitudes and Behaviors for A New Generation: Are They Really Changing? *College Student Behavior*, 1991.

- Oklahoma State Department of Health. Primary prevention for reducing firearm related morbidity and mortality. Research data collected for state health department. 1994-1995.

- Simms, J. Paul, PhD.; **Schoondyke Jeffrey, W., MD, MPH**. Use of a Personal Digital Assistant (PDA) to Monitor Vital Patient Functions in a Medical-Evacuation setting.

- **Schoondyke Jeffrey W., MD, MPD**; Hubbs Doris, MD; Ridgeway Nathan, MD,FACP. Preventable Rhabdomyolysis in Prison Inmates. *Journal of the Tennessee Medical Association.* Sept. 2001. Vol. 94. No. 9. 337-338.

- **Schoondyke Jeffrey W., MD, MPH**; Mohan Rajesh, MD; Appakondu Sirinivasa, MD; Sandhu Dalpinder, MD; Downs Chris, MD; Ponder Michael, MD, FACC. Elevated Troponin-I in a Patient With Acute Pulmonary Embolism Without Evidence of Coronary Artery Disease - Review of the literature and description of a case presenting with chest pain, acute onset shortness of breath and hypoxia. *Journal of the Tennessee Medical Association, April 2002.*

- **Schoondyke Jeffrey W., MD, MPH**. Fosinopril Induced Hepatotoxicity in a Complex Medical Patient. *Journal of the Tennessee Medical Association May 2002.*

- **Schoondyke, Jeffrey W., MD, MPH**; Burress, Jonathan, DO.; Shabaneah, Baha, MD; Fahrig, Stephen A. MD; Whitaker, Jack, MD. Papillary Fibroelastoma involving the Left Ventricular Wall. *Cardiovascular Reviews*, 2003.

- Abi-Saleh B, Isakandar SB, **Schoondyke JW**, Fahrig, S. Tako-tsubo syndrome as a consequence of transient ischemic attack. Rev Cardiovasc Med. 2006 Winter;7(1):37-41. PMID: 1653449eb

- Mechleb BK, Kasasbeh ES, Iskandar SB, **Schoondyke JW**, Garcia ID. Mitral Valve Prolapse: Relationship of echocardiography characteristics to natural history. Echocardiography. 2006 May;23(5):434-437. PMID: 16686634

- Abi-Saleh B, **Schoondyke JW**, Abboud L, Downs CJ, Haddadin TZ, Iskandar SB. Tricuspid valve involvement in carcinoid disease. Echocardiography. 2007 Apr;24(4):439-442. PMID:17381657

- **Schoondyke, Jeffrey W., MD, MPH, FACC;** Kari's Story- Daddy's Little Girl. Voice Magazine for Women. June 2009 p.5-6.

- **Schoondyke, Jeffrey W., MD, MPH, FACC;** Physician Spotlight. East Tennessee Medical News. June 2009. Pg 5-9.

- **Schoondyke, Jeffrey W., MD, MPH, FACC;** Physician to Physician: Patients versus Process. East Tennessee Medical News. February, 2010.

Clinical Trial Research

- Principle Investigator- CURRENT Trial 2007
- Sub-PI Timi 48 Trial 2008-2009
- Medtronic Optivol Trial 5/2009
- PI Novartis LCZ 676 Clinical Trial 3/1010

Speakers Bureau

- Boehringer Ingelheim Pharmaceuticals 2007
- Pfizer Pharmaceuticals Since 2004
- Medtronic 2007
- Molecular Imaging Alliance 2010

Honors and Scholarship

- Dean's List- Northern Arizona University, 1989-1992.
- Annual Undergraduate Research Award – Northern Arizona University 1992.
- Outstanding Psychology Student- Northern Arizona University 1992.
- Dean's List- St. George's University School of Medicine 1996-99.
- Chief Resident- Johnson City Medical Center. East Tennessee State University, Dept of Internal Medicine. 2001-2002.
- Chief of Chief Residents- East Tennessee State University College of Medicine. 2001-2002.

- ICGME Resident Representative. East Tennessee State University. 2001- 2002.
- Chief Cardiology Fellow- East Tennessee State University 2004-2005.
- Business Journal Healthcare Hero Award Recipient 2009.
- Medical Director Mountain States Medical Group- Cardiology 2009.
- Medical Director Molecular Imaging Alliance 2010.
- National Cardiology Advisor Nuclear Medicine- Molecular Imaging Alliance 2010.
- Vice-Chair Department of Cardiology Mountain States Medical Center 2012-2014.
- Most Loved Provider from Project Access 2012.

Volunteer Work

- President, Kari's Heart Foundation, Inc. A non-profit 501c3 charitable organization which provides assistance to the families of hospitalized children. 8/2008- Present.
- March of Dimes 2009 & 2010.
- Project Access: A non-profit service for underserved individuals within the healthcare system.

References Available On Request

141 BAREFOOT LANDING DRIVE•BLOUNTVILLE•TENNESSEE•37617
PHONE (423) 737-2912 • E-MAIL MDAVID76@GMAIL.COM

MELANIE R DAVIDSON MD FACC

EDUCATION

2003-2006 East Tennessee State University Johnson City, Tennessee
Cardiology Fellowship
- Chief Cardiology Fellow 2005-2006

2000-2003 Cedars Sinai Medical Center Los Angeles, California
Internal Medicine Residency
- UCLA Affiliate

1996-2000 Loma Linda University Loma Linda, California
Medical School–M.D.
- Internal Medicine with Distinction
- MacKenzie Foundation Scholarship 1999

1994-1996 Loma Linda University Loma Linda, California
B.S./Clinical Laboratory Science
- Graduated with Honors
- Class Secretary 1995-1996
- Moncrieff Scholarship 1996
- Moncrieff Scholarship 1995

1992-1994 La Sierra University Riverside, California
Pre-medicine, Clinical Laboratory Science major
- Dean's List of Academic Honors

PROFESSIONAL EXPERIENCE

8/2006-Current MSMG Cardiology Kingsport, Tennessee
Invasive Non-Interventional Cardiologist
- Cath Lab Director, Indian Path Medical Center 2008-2009

1996-1998 Riverside Community Hospital Riverside, California
Clinical Laboratory Scientist

1994-1996 Huntington East Valley Hospital Glendora, California
Laboratory Assistant

LICENSING INFORMATION

Fellow of the American College of Cardiology	2009
Board Certification for Cardiovascular disease	2006-2016
Board Certification for Internal Medicine	2003-12/2013
CA Licensing Exam for Clin. Lab. Scientist	Passed 1999
ASCP Licensing Exam	Passed 1999
TN State Medical License 37717	Exp. 7/31/14
VA State Medical License 0101237859	Exp. 7/31/14
DEA# BD9113856	Exp. 6/30/16
ACLS Certified	Exp. 1/2015

PROFESSIONAL MEMBERSHIPS

American College of Cardiology	2003-Present

SKILLS

Echocardiogram interpretation
Transesophageal Echocardiogram
Cardioversions
Exercise stress testing
Pharmacologic stress testing
Nuclear imaging interpretation
PET imaging interpretation
Cardiac Catheterization
ECG, Holter, and Event Monitor interpretation
Tilt Table Testing
Pacemaker Implantation

C, Need--1.A.3.e.
Letters of Intent

11/14/2013

Rob Gregory – Lifescan Tennessee dba Molecular Imaging Alliance
830 Suncrest Dr. Ste 2
Gray, TN 37615

Re: CN1304-014

To whom it may concern,

Upon installation and implementation of Karing Hearts Cardiology Cardiac PET service, Lifescan Tennessee, LLC will surrender for voidance CN1304-014 that approves the relocation of existing ODC from Gray, TN to Johnson City, TN. The ODC will be closed, not be relicensed and will not seek to replace the imaging equipment.

Please let me know if further information is required.

Kind regards,

Rob Gregory – Lifescan Tennessee dba Molecular Imaging Alliance
President/Owner

Precision Nuclear, LLC

October 31, 2013

Dr. Jeffrey Schoondyke
Karing Hearts Cardiology
701 N. State of Franklin, Suite 2
Johnson City, TN 37604

Dear Dr. Schoondyke:

This letter is to confirm the ability and willingness of Precision Nuclear, LLC to supply your PET imaging system at Karing Hearts Cardiology with unit dose [N13]NH_3 Ammonia for cardiac PET perfusion imaging for the calendar years of 2013 and 2014. Their proposed location is in Johnson City, Tennessee, should their relocation from the existing location in Gray, Tennessee, be approved by the State of Tennessee. If you have any questions or concerns, please do not hesitate to contact me directly.

Sincerely,

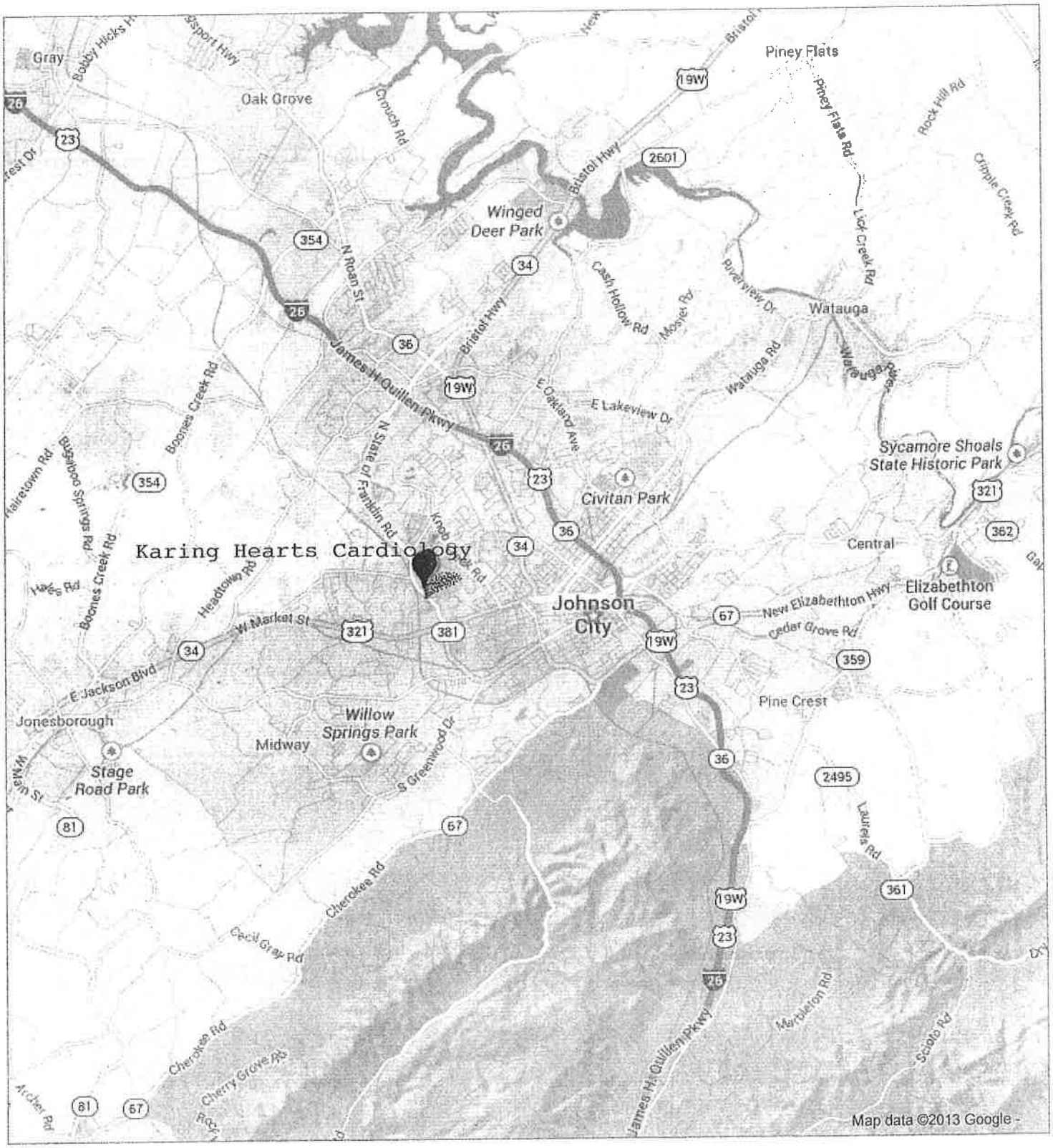
Alan W. Arp, Pharm.D.
President, Precision Nuclear, LLC

830 Suncrest Drive, Unit #1 Gray, Tennessee 37615 Phone: (423) 477-2440 Fax: (423) 477-3233

C, Need--3
Service Area Maps

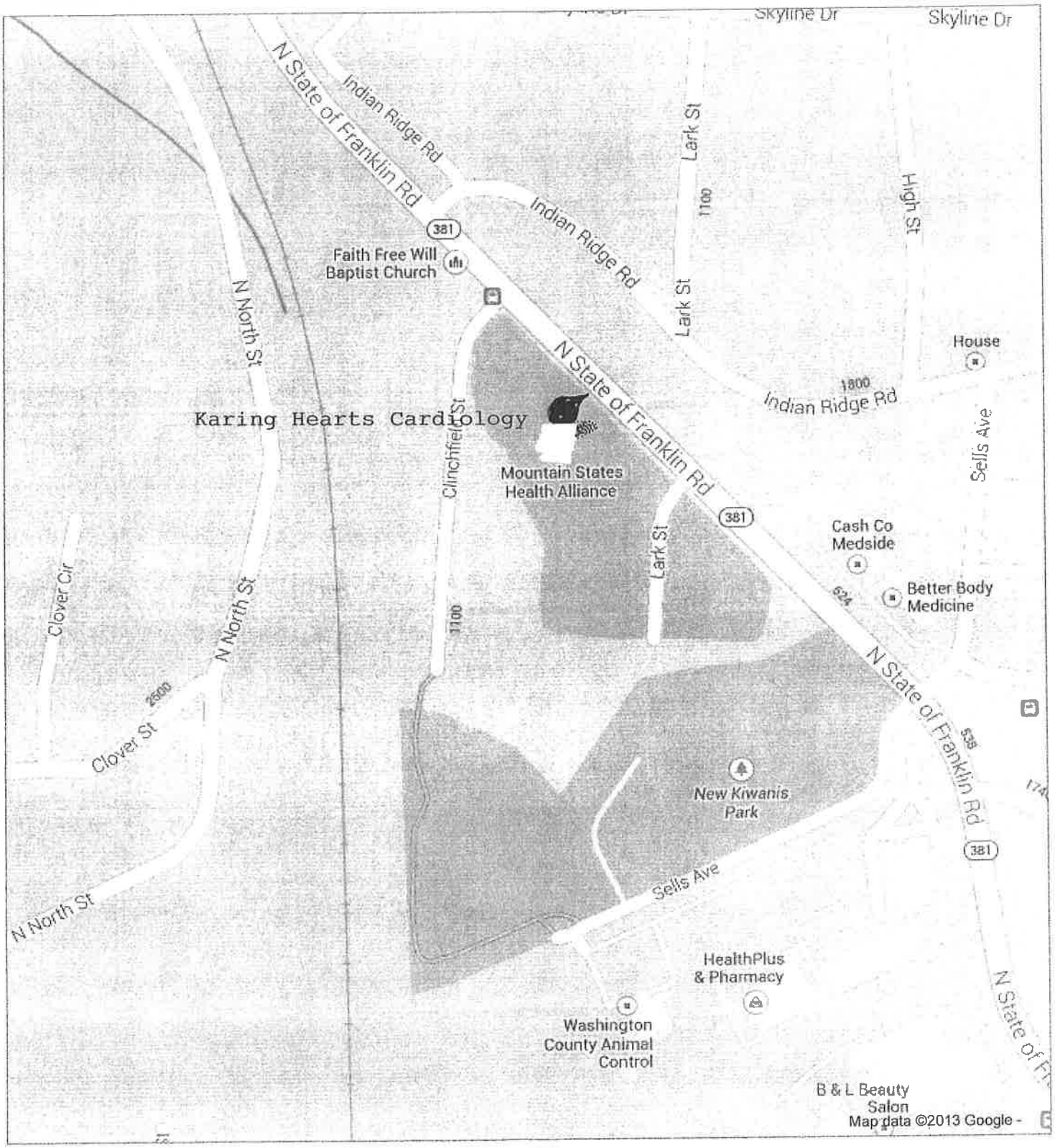
To see all the details that are visible on the screen, use the "Print" link next to the map.

Google

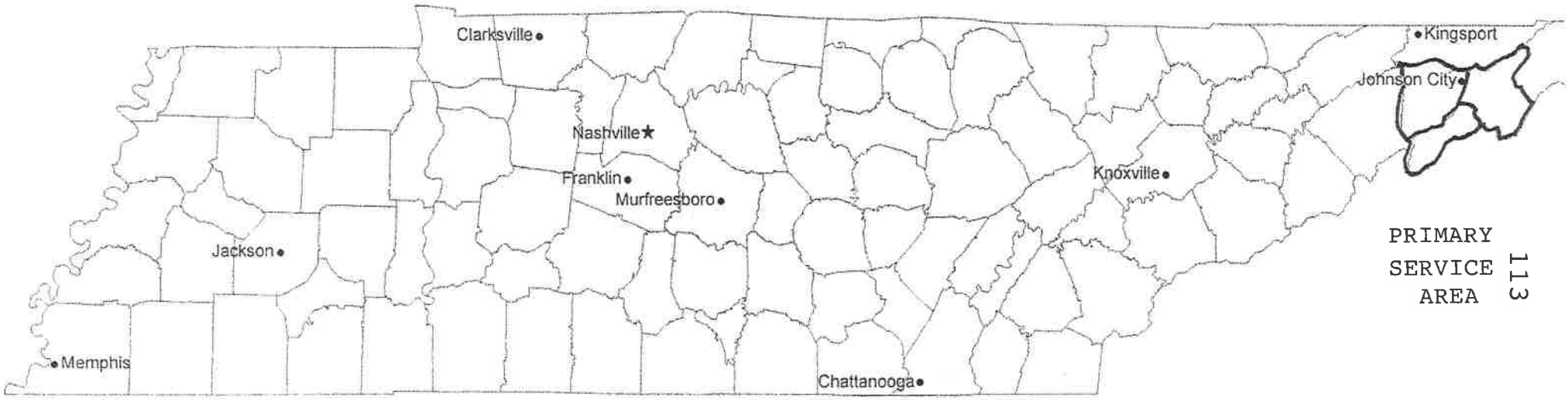


To see all the details that are visible on the screen, use the "Print" link next to the map.

Google



Karing Hearts Cardiology Cardiac PET Service



Karing Hearts Cardiology Cardiac PET Service

PRIMARY SERVICE AREA

114

Get Printable Maps From:
Waterproof Paper.com

C, Economic Feasibility--1
Documentation of Construction Cost Estimate

MITCH COX
COMPANIES

November 12, 2013

Mr. Rob Gregory
Karing Hearts Cardiology
701 N. State of Franklin Road, Suite 2
Johnson City, TN 37604

Subject: Verification of Construction Cost Estimate
Installation of P.E.T. Imaging System
Johnson City, Tennessee

Rob,

I have reviewed the cost data for the above-referenced project, for which our firm has provided a preliminary design. The stated renovation construction cost is approximately $100,000.00 [In providing opinions of probably construction cost, the Client understands that the Consultant has no control over the cost or availability of labor, equipment of materials, or over market conditions of the selected contractor's method of pricing, and that the Consultant's opinions of probable construction costs are made on the basis of the Consultant's professional judgment and experience. The Consultant makes no warranty, express or implied, that the bids of negotiated cost of the work will not vary from the Consultant's opinion of probable construction cost.]

It is our opinion that at this time, the projected renovated construction cost is reasonable for this type and size of project and compares appropriately with similar projects in this market.

The current building codes applicable to the project, as of the date of this letter, will be;

- 2006 International Building Codes (Bldg., Mechanical, Gas, Etc.)
- 2006 National Fire Protection Association Codes (including Life Safety Code)
- 2002 North Carolina Accessibility Code with 2004 amendments.
- National Electric Code
- Americans with Disabilities Act (ADA)

This listing is not entirely inclusive, but the intent is for all applicable codes and standards, State and local, to be addressed during the design process. The codes in effect at the time of submittal of plans and specifications shall be the codes to be used throughout the project.

Sincerely,

Michael J. Cannon

Michael J Cannon

Architect, TN License #17,125

O 423.282.6582
F 423.282.5903
www.mitchcox.com
801 Sunset Drive, Suite D-1
Johnson City, TN 37604

C, Economic Feasibility--2
Documentation of Availability of Funding

MCB
MOUNTAIN COMMERCE BANK

November 12, 2013

Melanie M. Hill, Executive Director
Tennessee Health Services and Development Agency
Frost Building, Third Floor
161 Rosa Parks Boulevard
Nashville, Tennessee 37203

RE: Karing Hearts Cardiology, PLLC

Dear Ms. Hill:

This letter is to provide assurance that Mountain Commerce Bank is familiar with the subject project, which is being proposed by Karing Hearts Cardiology.

Upon submittal and approval of a formal financing application, we would expect to be able to provide both construction and permanent financing for this project. We understand that the financing required would total $139,000.00 of initial funding.

The loan package on this project would of course reflect market conditions at the time of loan approval. Currently we would expect to finance this type of project at an interest rate of approximately 4.75% for a term of 10 Years. Attached is an amortization schedule reflecting that estimate.

We look forward to helping with the financing of this project.

Sincerely,

Bobby A. Brown
Senior Vice President

3122 Bristol Highway Johnson City TN 37601
PH: 423-232-5002

Prepared For Karing Hearts Cardio
Platform Type CR
Account #

Officer BAB
Rate 4.750000% Payment 1,461.92
APR 4.8173% Interest 36,430.50

CSR S67RBOWEN
Term 120 Payment Day:

Date	Number	Payment Misc.	Payment Interest	Payment Principal	Payment PMI Ins.	Total	Balance
					Original Balance		139,000.00
12/18/13	1	.00	550.21	911.71	.00	1,461.92	138,088.29
Year 2013		.00	550.21	911.71	.00	1,461.92	
1/18/14	2	.00	564.82	897.10	.00	1,461.92	137,191.19
2/18/14	3	.00	561.15	900.77	.00	1,461.92	136,290.42
3/18/14	4	.00	503.52	958.40	.00	1,461.92	135,332.02
4/18/14	5	.00	553.54	908.38	.00	1,461.92	134,423.64
5/18/14	6	.00	532.09	929.83	.00	1,461.92	133,493.81
6/18/14	7	.00	546.03	915.89	.00	1,461.92	132,577.92
7/18/14	8	.00	524.79	937.13	.00	1,461.92	131,640.79
8/18/14	9	.00	538.45	923.47	.00	1,461.92	130,717.32
9/18/14	10	.00	534.67	927.25	.00	1,461.92	129,790.07
10/18/14	11	.00	513.75	948.17	.00	1,461.92	128,841.90
11/18/14	12	.00	527.00	934.92	.00	1,461.92	127,906.98
12/18/14	13	.00	506.30	955.62	.00	1,461.92	126,951.36
Year 2014		.00	6,406.11	11,136.93	.00	17,543.04	
1/18/15	14	.00	519.26	942.66	.00	1,461.92	126,008.70
2/18/15	15	.00	515.41	946.51	.00	1,461.92	125,062.19
3/18/15	16	.00	462.04	999.88	.00	1,461.92	124,062.31
4/18/15	17	.00	507.45	954.47	.00	1,461.92	123,107.84
5/18/15	18	.00	487.30	974.62	.00	1,461.92	122,133.22
6/18/15	19	.00	499.56	962.36	.00	1,461.92	121,170.86
7/18/15	20	.00	479.63	982.29	.00	1,461.92	120,188.57
8/18/15	21	.00	491.61	970.31	.00	1,461.92	119,218.26
9/18/15	22	.00	487.63	974.29	.00	1,461.92	118,243.97
10/18/15	23	.00	468.05	993.87	.00	1,461.92	117,250.10
11/18/15	24	.00	479.59	982.33	.00	1,461.92	116,267.77
12/18/15	25	.00	460.22	1,001.70	.00	1,461.92	115,266.07
Year 2015		.00	5,857.75	11,685.29	.00	17,543.04	
1/18/16	26	.00	471.47	990.45	.00	1,461.92	114,275.62
2/18/16	27	.00	467.42	994.50	.00	1,461.92	113,281.12
3/18/16	28	.00	433.46	1,028.46	.00	1,461.92	112,252.66
4/18/16	29	.00	459.15	1,002.77	.00	1,461.92	111,249.89
5/18/16	30	.00	440.36	1,021.56	.00	1,461.92	110,228.33
6/18/16	31	.00	450.86	1,011.06	.00	1,461.92	109,217.27
7/18/16	32	.00	432.32	1,029.60	.00	1,461.92	108,187.67
8/18/16	33	.00	442.52	1,019.40	.00	1,461.92	107,168.27
9/18/16	34	.00	438.35	1,023.57	.00	1,461.92	106,144.70
10/18/16	35	.00	420.15	1,041.77	.00	1,461.92	105,102.93
11/18/16	36	.00	429.91	1,032.01	.00	1,461.92	104,070.92
12/18/16	37	.00	411.94	1,049.98	.00	1,461.92	103,020.94
Year 2016		.00	5,297.91	12,245.13	.00	17,543.04	

C, Economic Feasibility--10
Financial Statements

Charles F. Bolton, (1928-2008)

Kimberly D. Coker, CPA

Gregory M. DeGennaro, CPA

BCD
Bolton • Coker • DeGennaro
CERTIFIED PUBLIC ACCOUNTANTS

Members
American Institute and
Tennessee Society of
Certified Public Accountants

To the Owner
Karing Hearts Cardiology, PLLC
Johnson City, TN

We have compiled the accompanying balance sheet of Karing Hearts Cardiology, LLC (a sole proprietorship) as of October 31, 2013 and related statement of income for the ten months then ended. We have not audited or reviewed the accompanying financial statements and, accordingly, do not express an opinion or provide any assurance about whether the financial statements are in accordance with accounting principles generally accepted in the United States of America.

The owner is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America and for designing, implementing, and maintaining internal control relevant to the preparation and fair presentation of the financial statements.

Our responsibility is to conduct the compilation in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants. The objective of a compilation is to assist the owner in presenting financial information in the form of financial statements without undertaking to obtain or provide any assurance that there are no material modifications that should be made to the financial statements.

The owner has elected to omit substantially all the disclosures and the statements of proprietor's capital and cash flows required by accounting principles generally accepted in the United States of America. If the omitted disclosures and statements of proprietor's capital and cash flows were included in the financial statements, they might influence the user's conclusions about the Company's financial position, result of operations, and cash flows. Accordingly, the financial statements are not designed for those who are not informed about such matters.

Kimberly D. Coker, CPA

Bolton, Coker and DeGennaro, CPAs, P.C.

November 5, 2013

Karing Hearts Cardiology, PLLC
Balance Sheet
As of October 31, 2013

11/11/13
Cash Basis

	Oct 31, 13
ASSETS	
Current Assets	
Checking/Savings	
Bank of Tennessee	36,968.03
Bank of TN - EFT	132.16
Mountain Commerce - Dental	2,948.66
Mountain Commerce Bank-Investme	4,750.00
Mountain Commerce Bank - Oper	15,118.30
Petty Cash	2,769.00
Total Checking/Savings	62,686.15
Other Current Assets	
Employee Loan	250.00
Loan Rec. - Genesis	9,734.00
Total Other Current Assets	9,984.00
Total Current Assets	72,670.15
Fixed Assets	
Accumulated Depreciation	-85,871.00
Building	22,211.17
Furniture and Equipment	119,057.98
Leasehold Improvements	117,919.92
Medical Equipment	78,434.90
Total Fixed Assets	251,752.97
Other Assets	
Accumulated Amortization	-2,567.00
Loan Costs	3,579.86
Organization Costs	22,000.00
Total Other Assets	23,012.86
TOTAL ASSETS	**347,436.98**
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Accounts Payable	
Accounts Payable	4,742.57
Total Accounts Payable	4,742.57
Other Current Liabilities	
Bank of Tennessee - LOC	20,000.00
Payroll Liabilities	
After Tax Dental Fund	2,849.36
Employee Benefits	
Section 125 - Health Insurance	1,561.76
Total Employee Benefits	1,561.76
Payroll Taxes	
FUTA Company	56.77
SUTA Company	312.32
Virignia Income Tax W/H	176.00
Total Payroll Taxes	545.09
Payroll Liabilities - Other	4,750.00
Total Payroll Liabilities	9,706.21
Total Other Current Liabilities	29,706.21
Total Current Liabilities	34,448.78

See accountants' compilation report.

11/11/13
Cash Basis

Karing Hearts Cardiology, PLLC
Balance Sheet
As of October 31, 2013

	Oct 31, 13
Long Term Liabilities	
Bank of TN - Capital Loan	325,543.86
Total Long Term Liabilities	325,543.86
Total Liabilities	359,992.64
Equity	
Members Equity	-123,492.49
Net Income	110,935.83
Total Equity	-12,556.66
TOTAL LIABILITIES & EQUITY	347,436.98

See accountants' compilation report.

Karing Hearts Cardiology, PLLC
Profit & Loss
January through October 2013

11/11/13
Cash Basis

		Jan - Oct 13
Ordinary Income/Expense		
Income		
Practice Receipts		1,470,138.46
Refunds		-1,100.03
Total Income		1,469,038.43
Gross Profit		1,469,038.43
Expense		
Advertising and Promotion		12,452.59
Answering Service		1,654.79
Automobile Expense		170.59
Bank Service Charges		2,302.97
Billing Fees		22,937.03
Business Gifts		49.22
Business Licenses and Permits		150.00
Charitable Donations		14,491.62
Clinical Supplies		29,416.11
Computer and Internet Expenses		27,113.96
Continuing Education		3,301.22
Contractual Services		
Echo Technician	5,302.56	
Interpreter	110.17	
Contractual Services - Other	1,250.00	
Total Contractual Services		6,662.73
Dues and Memberships		4,306.27
Equipment Rental		1,555.61
Insurance Expense		
Business and Property	696.90	
Life Insurance	1,407.16	
Malpractice Insurance	19,311.00	
Total Insurance Expense		21,415.06
Interest Expense		12,925.33
Janitorial Expense		8,555.52
Laboratory Fees		673.25
Meals and Entertainment		17,085.23
Office Supplies		21,633.33
Payroll Expenses		
Employee Benefits		
Health Insurance	30,703.46	
Total Employee Benefits		30,703.46
Employee Salaries and Wages		
Employee Salaries	216,456.25	
Employee Wages	250,686.59	
Total Employee Salaries and Wages		467,142.84
Payroll Taxes		
Federal Unemployment	666.91	
FICA - Medicare	11,665.65	
FICA - Social Security	35,293.42	
TN Unemployment	3,759.92	
Total Payroll Taxes		51,385.90
Payroll Expenses - Other		2,211.55
Total Payroll Expenses		551,443.75
Postage and Shipping		2,439.70
Printing		1,809.54
Processing Fees		1,199.30
Professional Fees		
Accounting Services		12,780.00

See accountants' compilation report.

Karing Hearts Cardiology, PLLC
Profit & Loss
January through October 2013

11/11/13
Cash Basis

	Jan - Oct 13
Total Professional Fees	12,780.00
Rent Expense	47,464.59
Repairs and Maintenance	12,734.99
Retirement Plan Administration	1,224.00
Security Expense	563.80
Small Medical Equipment	1,639.43
Taxes	
Franchise/Excise	2,022.00
Professional Privilege	1,970.00
Total Taxes	3,992.00
Telephone Expense	10,901.51
Travel Expense	7,651.84
Uniforms	1,520.56
Uniforms/Clothing	208.87
Utilities	
Electricity	17,291.15
Gas	2,205.14
Total Utilities	19,496.29
Total Expense	885,922.60
Net Ordinary Income	583,115.83
Other Income/Expense	
Other Expense	
Owner Draws	119,900.00
Owner Salary	352,280.00
Total Other Expense	472,180.00
Net Other Income	-472,180.00
Net Income	110,935.83

Karing Hearts Cardiology, PLLC
Balance Sheet
As of December 31, 2012

Cash Basis

	Dec 31, 12
ASSETS	
Current Assets	
Checking/Savings	
Bank of Tennessee	13,808.73
Mountain Commerce - Dental	2,148.66
Mountain Commerce Bank - Oper	20,161.30
Petty Cash	2,519.00
Total Checking/Savings	38,637.69
Total Current Assets	38,637.69
Fixed Assets	
Accumulated Depreciation	-85,871.00
Furniture and Equipment	114,423.32
Leasehold Improvements	66,894.60
Total Fixed Assets	95,446.92
Other Assets	
Accumulated Amortization	-2,567.00
Organization Costs	22,000.00
Total Other Assets	19,433.00
TOTAL ASSETS	**153,517.61**
LIABILITIES & EQUITY	
Liabilities	
Current Liabilities	
Accounts Payable	
Accounts Payable	1,246.76
Total Accounts Payable	1,246.76
Other Current Liabilities	
Payroll Liabilities	
After Tax Dental Fund	2,049.36
Employee Benefits	
Section 125 - Health Insurance	800.72
Total Employee Benefits	800.72
Payroll Taxes	
FUTA Company	50.26
SUTA Company	311.60
Virignia Income Tax W/H	156.00
Total Payroll Taxes	517.86
Payroll Liabilities - Other	170.00
Total Payroll Liabilities	3,537.94
Total Other Current Liabilities	3,537.94
Total Current Liabilities	4,784.70
Long Term Liabilities	
Bank of TN - Capital Loan	272,225.40
Total Long Term Liabilities	272,225.40
Total Liabilities	277,010.10
Equity	
Members Draw	-59,443.96
Members Equity	-101,175.51
Net Income	37,126.98
Total Equity	-123,492.49
TOTAL LIABILITIES & EQUITY	**153,517.61**

Karing Hearts Cardiology, PLLC
Profit & Loss
January through December 2012

Cash Basis

		Jan - Dec 12
Ordinary Income/Expense		
Income		
Practice Receipts		1,380,638.22
Refunds		-1,261.32
Total Income		1,379,376.90
Gross Profit		1,379,376.90
Expense		
Advertising and Promotion		22,954.31
Amortization Expense		1,467.00
Answering Service		2,136.30
Bank Service Charges		2,480.48
Billing Fees		39,788.29
Books and Manuals		173.16
Business Gifts		120.00
Charitable Donations		15,365.20
Clinical Supplies		12,360.31
Computer and Internet Expenses		4,245.41
Continuing Education		2,085.00
Contractual Services		7,380.00
Depreciation Expense		77,965.00
Dues and Memberships		8,673.40
Insurance Expense		
Business and Property	599.00	
Malpractice Insurance	14,614.00	
Insurance Expense - Other	3,143.89	
Total Insurance Expense		18,356.89
Interest Expense		17,130.43
Janitorial Expense		1,500.00
Laboratory Fees		318.25
Leasehold Imp Abandonment		28,253.00
Meals and Entertainment		6,245.37
Office Supplies		37,059.04
Payroll Expenses		
Employee Benefits		
Employee Relocation Expense	3,219.00	
Health Insurance	25,141.02	
Total Employee Benefits		28,360.02
Employee Salaries and Wages		
Employee Salaries	286,172.21	
Employee Wages	220,164.22	
Total Employee Salaries and Wages		506,336.43
Payroll Taxes		
Federal Unemployment	616.56	
FICA - Medicare	11,686.28	
FICA - Social Security	35,740.33	
TN Unemployment	3,414.50	
Total Payroll Taxes		51,457.67
Payroll Expenses - Other		1,029.94
Total Payroll Expenses		587,184.06
Postage and Shipping		909.19
Printing		1,537.12
Processing Fees		1,600.00
Professional Fees		
Accounting Services	7,495.00	
Legal Fees	14,900.00	
Professional Fees - Other	3,584.00	
Total Professional Fees		25,979.00

Karing Hearts Cardiology, PLLC
Profit & Loss
January through December 2012

Cash Basis

		Jan - Dec 12
Rent Expense		37,021.04
Repairs and Maintenance		10,391.96
Retirement Plan Administration		1,224.00
Taxes		
Franchise/Excise	575.00	
Professional Privilege	400.00	
Total Taxes		975.00
Telephone Expense		18,076.88
Travel Expense		8,644.89
Uniforms		231.02
Uniforms/Clothing		4,179.96
Utilities		
Cable and Internet	6,961.54	
Electricity	6,822.99	
Gas	892.89	
Total Utilities		14,677.42
Total Expense		1,018,688.38
Net Ordinary Income		360,688.52
Other Income/Expense		
Other Expense		
Owner Salary		323,561.54
Total Other Expense		323,561.54
Net Other Income		-323,561.54
Net Income		37,126.98

Miscellaneous Information

Summaries from 2007 data

REVIEW ARTICLE

Recent advances in cardiac PET and PET/CT myocardial perfusion imaging

Gary V. Heller, MD, PhD,[a] Dennis Calnon, MD,[b] and Sharmila Dorbala, MD[c]

Cardiovascular imaging has gained an important role in the evaluation of patients with either known or suspected coronary artery disease. The choices have expanded, imaging procedures have improved. Currently, testing procedures include echocardiography, magnetic resonance imaging, cardiac CTA, cardiac catheterization, and nuclear myocardial perfusion imaging with either single photon emission computed tomography (SPECT) or positron emission tomography (PET). Each of these imaging modalities has its strengths and weaknesses. However, SPECT myocardial perfusion imaging has emerged as a reliable and widely available tool for physicians to use in the assessment of their patient for the exclusion or presence and severity of CAD. Recently, cardiac PET has emerged as an alternative to SPECT imaging.

Cardiac positron emission tomography (PET) imaging has gained considerable support and use in the field of cardiovascular imaging over the past several years. For example, delivery of the most accessible PET tracer, Rubidium-82 (RB-82) has quadrupled; the use of myocardial viability studies has increased, and the value of cardiac PET perfusion imaging is now being recognized. This recent increase in activity and interest has been spearheaded by several factors, such as availability of the camera technology, advances in cardiac PET acquisition and perfusion procedures, improved display procedures and software, as well as literature supporting the diagnostic and prognostic accuracy of PET perfusion imaging. This review will highlight cardiac PET as presented in a recent symposium with regards to differences between SPECT imaging and PET, literature supporting cardiac PET for both diagnostic accuracy and risk stratification, and features of cardiac PET/CT that differentiate it from SPECT. The review includes recent literature advances.

From the Nuclear Cardiology Laboratory, Henry Low Heart Center,[a] Hartford Hospital, Hartford, CT; Nuclear Cardiology Laboratory,[b] McConnell Heart Hospital at Riverside Methodist Hospital, Columbus, OH; Nuclear Medicine Laboratory,[c] Brigham and Women s Hospital, Boston, MA.

The review includes a summary of presentations made by the authors at a symposium sponsored by the same organization at the Annual Scientific Sessions of ASNC in San Diego, September 10-14, 2007 as well as recent advancements in the literature.

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1071-3581/$34.00

doi:10.1007/s12350-009-9142-5

SINGLE-PHOTON-COMPUTED TOMOGRAPHIC IMAGING: STRENGTHS AND WEAKNESSES

Single-photon-computed tomographic imaging (SPECT) has been successfully performed for over 30 years. Over 6 million studies are performed annually with a rich literature confirming both diagnostic and accuracy prognostic value. Over these years, considerable advancement has been made in the technology to improve image quality and shorten acquisition protocols. Its strengths are many including standardized protocols, ease of use, availability, and established guidelines (Table 1).

Despite these advances, however, several limitations of SPECT remain (Table 2). It is well recognized that SPECT techniques frequently underestimate the degree of ischemia and therefore the presence of multivessel coronary artery disease. The stress imaging protocols are inefficient and require much longer time than similar protocols for echo, CT, or even cardiac catheterization (2.5-4 vs 1 hour or less for other procedures). Recent advancements have targeted these long procedures including shortened acquisition times, as recently summarized by Slomka et al.[1] Attenuation artifact with SPECT imaging is commonplace despite efforts to identify using techniques such as prone imaging, attenuation correction, and/or ECG-gated SPECT imaging. Tracer activity in the liver and gut structures are common with SPECT imaging, particularly popular technetium-based imaging agents. As a result, interpretative confidence is sometimes lacking.

CARDIAC PET PERFUSION IMAGING AS AN ALTERNATIVE TO SPECT

An alternative to SPECT imaging is cardiac PET perfusion imaging. PET offers many advantages (Table 3). These advantages include higher spatial and contrast resolution, resulting in higher image quality and

Journal of Nuclear Cardiology
Volume 16, Number 6;962–9

Table 1. Strengths of SPECT myocardial perfusion imaging

Standardized protocols
Small, relatively inexpensive camera systems suitable for offices
Well documented literature for diagnostic accuracy
Well documented literature for risk stratification
ACC/ASNC guidelines, appropriateness criteria
Great acceptance by cardiology community

Table 2. Limitations of SPECT myocardial perfusion imaging

SPECT techniques underestimate ischemia severity
Imaging protocols are inefficient (commonly 2-4 hours)
Attenuation artifacts are common
GI tracer interference is common
Interpretation confidence is often lacking

Table 3. Advantages of cardiac PET and PET/CT

Improved image quality
Higher spatial and contrast resolution
Accurate attenuation correction
Higher diagnostic accuracy
Excellent risk stratification
Rapid procedure
Rest and peak stress gating
Added information: blood flow, calcium, coronary CT

improved diagnostic accuracy. Attenuation correction, a technique validated with SPECT but infrequently used, is performed on every PET perfusion study. Excellent data are emerging with regards to risk stratification with PET perfusion. With Rb-82 as the radiotracer, the procedure is rapid (30-40 minutes, in comparison to 2.5-4 hours). Finally, added information such as regional blood flow, calcium scoring, and coronary CT can be provided, depending on instrumentation.

ADVANTAGES OF PET PERFUSION IMAGING

Improved Image Quality

The higher energy level of PET radiopharmaceutical activity (511 vs 140 keV for technetium) provides markedly improved image quality due to higher spatial resolution, less scatter, and common use of attenuation correction. These factors improve image quality and markedly reduce attenuation artifact. Image quality was recently studied by Yoshinaga et al[2] in which patients with equivocal SPECT studies were referred for cardiac PET imaging. In very high percentage of patients, the PET study patient resulted in good to excellent image quality, 90% for PET, 20% for SPECT (Figure 1). In that study, there was an obvious referral bias, but still demonstrated striking differences in quality in the same patient. Using a comparison of similar but matched patients undergoing SPECT or PET, Bateman, et al[3] also reported a significant improvement in image quality with PET.

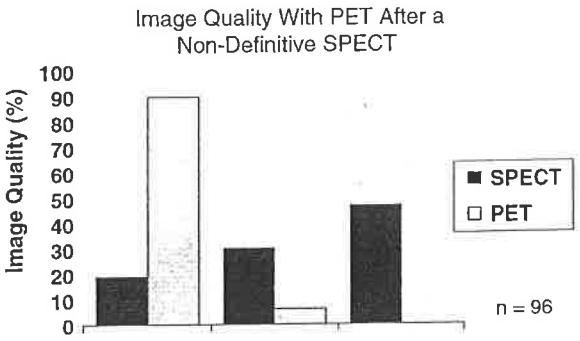

Figure 1. Comparison of image quality in patients undergoing SPECT and PET imaging. Adapted from Yoshinaga et al[2].

Attenuation artifact has been a major interpretation challenge for SPECT imaging. Because of the higher imaging activity of the radiopharmaceutical tracer as well as attenuation correction, PET imaging is far less susceptible to attenuation artifact. A recent study by Bateman et al[3] evaluated artifact a similar group of SPECT and PET patients. As shown in Table 4 the incidence of significant artifact was reduced as well as gut uptake and particularly that in which interpretation could be compromised. A common reason for PET imaging inconclusive studies is that of an inconclusive

Table 4. Comparison of artifact between SPECT and PET perfusion imaging

	SPECT	PET	*P* value
No artifact	19 (17%)	49 (44%)	.0001
Minor artifact	26 (23%)	28 (25%)	.75
Significant artifact	64 (57%)	33 (29%)	.0003
Major artifact	3 (3%)	2 (2%)	.32
No GI uptake	45 (40%)	100 (89%)	<.001
Minor GI uptake	19 (17%)	5 (4%)	.0002
Significant GI uptake	46 (41%)	6 (5%)	<.001
Major GI uptake	2 (2%)	1 (1%)	.32

SPECT, Single photon emission computed tomography; *PET*, positron emission tomography; *GI*, gastrointestinal (Bateman et al[3]).

ORIGINAL ARTICLES

Diagnostic accuracy of rest/stress ECG-gated Rb-82 myocardial perfusion PET: Comparison with ECG-gated Tc-99m sestamibi SPECT

Timothy M. Bateman, MD,[abc] Gary V. Heller, MD, PhD,[d] A. Iain McGhie, MD,[ac] John D. Friedman, MD,[e] James A. Case, PhD,[bc] Jan R. Bryngelson, BN,[b] Ginger K. Hertenstein, CNMT,[b] Kelly L. Moutray, MEd,[c] Kimberly Reid, MS,[c] and S. James Cullom, PhD[bc]

Background. **Although single photon emission computed tomography (SPECT) and positron emission tomography (PET) myocardial perfusion imaging (MPI) have evolved considerably over the last decade, there is no recent comparison of diagnostic performance. This study was designed to assess relative image quality, interpretive confidence, and diagnostic accuracy by use of contemporary technology and protocols.**

Methods and Results. **By consensus and without clinical information, 4 experienced nuclear cardiologists interpreted 112 SPECT technetium-99m sestamibi and 112 PET rubidium-82 MPI electrocardiography (ECG)–gated rest/pharmacologic stress studies in patient populations matched by gender, body mass index, and presence and extent of coronary disease. The patients were categorized as having a low likelihood for coronary artery disease (27 in each group) or had coronary angiography within 60 days. SPECT scans were acquired on a Cardio-60 system and PET scans on an ECAT ACCEL scanner. Image quality was excellent for 78% and 79% of rest and stress PET scans, respectively, versus 62% and 62% of respective SPECT scans (both $p < .05$). An equal percent of PET and SPECT gated images were rated excellent in quality. Interpretations were definitely normal or abnormal for 96% of PET scans versus 81% of SPECT scans ($p = .001$). Diagnostic accuracy was higher for PET for both stenosis severity thresholds of 70% (89% vs 79%, $p = .03$) and 50% (87% vs 71%, $p = .003$) and was higher in men and women, in obese and nonobese patients, and for correct identification of multivessel coronary artery disease.**

Conclusion. **In a large population of matched pharmacologic stress patients, myocardial perfusion PET was superior to SPECT in image quality, interpretive certainty, and diagnostic accuracy. (J Nucl Cardiol 2006;13:24-33.)**

Key Words: Single photon emission computed tomography • positron emission tomography • myocardial perfusion imaging

See related article, p. 2

Radionuclide myocardial perfusion imaging (MPI) is performed worldwide for assessing patients with known or suspected coronary artery disease (CAD). Most commonly, either thallium-201 or a technetium-99m perfusion tracer is used via single photon emission computed tomography (SPECT). An alternative is myocardial perfusion positron emission tomography (PET) using either cyclotron-produced ammonia or generator-produced rubidium 82.[1] There are several potential advantages of PET MPI, such as higher spatial resolution, greater counting efficiencies, and robust attenuation correction. All of these factors presumably form the basis of improved diagnostic accuracy in comparison to SPECT in studies performed more than a decade ago.[2-6] Although these studies were instrumental in shaping

From Cardiovascular Consultants, PC,[a] Cardiovascular Imaging Technologies, LLC,[b] and Mid America Heart Institute,[c] Kansas City, Mo, Division of Cardiology, Henry Low Heart Center, Hartford Hospital, Hartford, Conn,[d] and Cedars-Sinai Medical Center, Los Angeles, Calif.[e]

This work was supported in part by a grant from Bracco Diagnostics, Princeton, NJ.

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1071-3581/$32.00

doi:10.1016/j.nuclcard.2005.12.004

Impact of Myocardial Perfusion Imaging with PET and ^{82}Rb on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management

Michael E. Merhige[1,2], William J. Breen[†1,3], Victoria Shelton[2], Teresa Houston[3], Brian J. D'Arcy[1,3], and Anthony F. Perna[1]

[1]*Departments of Cardiology, Internal Medicine, and Nuclear Medicine, State University of New York at Buffalo, Buffalo, New York;* [2]*Heart Center of Niagara, Niagara Falls, New York; and* [3]*Buffalo Cardiology and Pulmonary Associates, Buffalo, New York*

We hypothesized that PET myocardial perfusion imaging with ^{82}Rb (PET MPI), would reduce downstream utilization of diagnostic arteriography, compared with SPECT, in patients matched for pretest likelihood of coronary disease (pCAD). PET MPI is more accurate for assessment of impaired coronary flow reserve compared with SPECT MPI, potentially reducing the demand for subsequent arteriography, percutaneous transcoronary intervention, and coronary artery bypass grafting (CABG), with attendant cost savings, while avoiding a negative impact on coronary events. **Methods:** The frequency of diagnostic arteriography, revascularization, costs, and 1-y clinical outcomes in 2,159 patients studied with PET MPI was compared with 2 control groups studied with SPECT MPI matched to the PET group by pCAD: an internal control group of 102 patients and an external SPECT control group of 5,826 patients. CAD management costs were approximated with realistic global fee estimates. **Results:** Arteriography rates were 0.34 and 0.31 for the external and internal control SPECT groups and 0.13 for the patients studied with PET ($P < 0.0001$). pCAD averaged 0.39 in patients studied with PET MPI, and in the external SPECT control group, and 0.37 in the internal SPECT controls. Revascularization rates were 0.13 and 0.11 for external and internal SPECT patients and 0.06 for the PET group ($P < 0.0001$; $P < 0.01$), with a cost savings of 30% noted for PET patients, with no significant difference in cardiac death or myocardial infaction at 1-y follow-up. **Conclusion:** PET MPI in patients with intermediate pCAD results in a >50% reduction in invasive coronary arteriography and CABG, a 30% cost savings, and excellent clinical outcomes at 1 y compared with SPECT.

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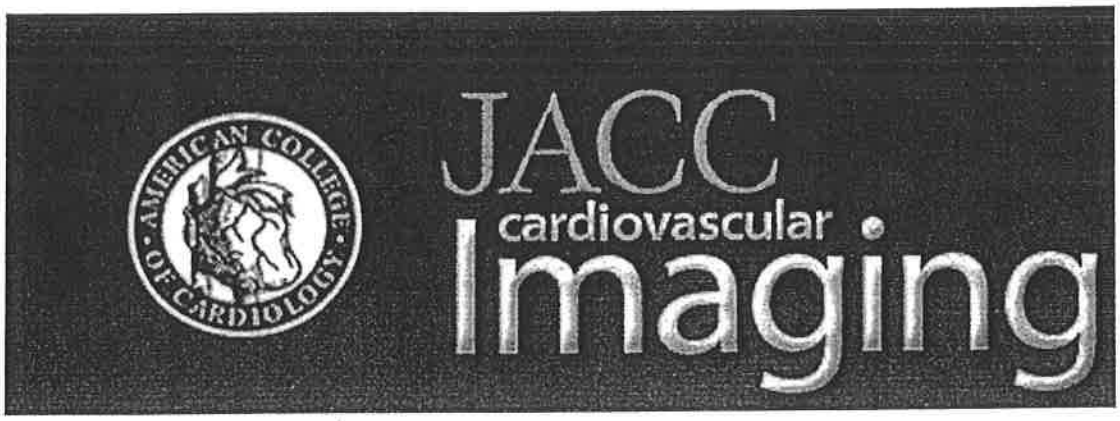
Compelling evidence has demonstrated that invasive procedures such as coronary arteriography, coronary artery bypass grafting (CABG), and percutaneous transcoronary intervention (PTCI) are overutilized in the United States, contributing to unnecessary health care expense without improved patient outcomes (*1–6*). Management of coronary disease (CAD) currently utilizes noninvasive diagnostic testing as a "gatekeeper," which typically provokes invasive coronary arteriography when results are abnormal, to provide a definitive diagnosis of CAD. Thereafter, mechanical myocardial revascularization is usually performed on the basis of the coronary lumenogram, often without improved outcome—specifically in the hard endpoints of coronary death and myocardial infarction (MI)—despite great cost (*7*). Previous theoretic models have indicated that increased diagnostic accuracy of noninvasive testing, specifically myocardial perfusion imaging using PET (PET MPI), may reduce costs and improve outcomes when used in place of SPECT (SPECT MPI), in the routine management of CAD (*8,9*), however, documentation of this hypothesis in a prospective trial has not been previously reported.

This study tests the hypothesis that a noninvasive strategy for CAD management using MPI, free of attenuation artifacts with improved resolution and image contrast due to substantially higher counts provided by PET, lowers costs of CAD management, through reduction of unnecessary downstream invasive diagnostic and therapeutic procedures, compared with conventional management with standard exercise SPECT, because of the improvement in diagnostic accuracy provided by PET.

In this study, clinical outcomes, procedure utilization, and costs were evaluated in 2,159 sequential patients imaged with PET MPI and compared with 2 control groups of patients, matched for pretest likelihood of CAD (pCAD), who were imaged with SPECT MPI.



Incremental Prognostic Value of Gated Rb-82 Positron Emission Tomography Myocardial Perfusion Imaging Over Clinical Variables and Rest LVEF

Sharmila Dorbala, Rory Hachamovitch, Zelmira Curillova, Deepak Thomas, Divya Vangala, Raymond Y. Kwong, and Marcelo F. Di Carli

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Incremental Prognostic Value of Gated Rb-82 Positron Emission Tomography Myocardial Perfusion Imaging Over Clinical Variables and Rest LVEF

Sharmila Dorbala, MD,*† Rory Hachamovitch, MD, MSc,‡ Zelmira Curillova, MD,*† Deepak Thomas, MD,* Divya Vangala,* Raymond Y. Kwong, MD,† Marcelo F. Di Carli, MD*†
Boston, Massachusetts; and Los Angeles, California

OBJECTIVES This investigation sought to study the incremental value of gated rubidium (Rb)-82 positron emission tomography (PET) myocardial perfusion imaging (MPI) over clinical variables for predicting survival and future cardiac events.

BACKGROUND The prognostic value of Rb-82 PET-MPI and left ventricular ejection fraction (LVEF) reserve (stress minus rest LVEF) is not well defined.

METHODS 1,432 consecutive patients undergoing gated rest/vasodilator stress rubidium-82 PET were followed up for at least 1 year. Of these, rest and peak stress LVEF and LVEF reserve were available in 985 patients. Cardiac events (CE) including cardiac death or nonfatal myocardial infarction and all-cause death were assessed.

RESULTS Over a mean follow-up of 1.7 ± 0.7 years, 83 (5.8%) CE and 140 (9.7%) all-cause death were observed. There was an increase in risk for both end points with an increasing percentage of abnormal and ischemic myocardium. With normal, mild, moderate, or severely ischemic scans, the observed annualized rates of CE were 0.7%, 5.5%, 5%, and 11% and of all-cause death were 3.3%, 7.2%, 6.9%, and 12.5%, respectively. In 985 patients with peak stress gated data, the observed annualized rates of CE (2.1% vs. 5.3%, $p < 0.001$) and all-cause death (4.3% vs. 9.2%, $p < 0.001$) were higher in patients with an LVEF reserve <0% compared with those with an LVEF reserve ≥0%. On Cox proportional hazards analysis, after consideration of clinical, historical, and rest LVEF information, stress PET results and LVEF reserve yielded incremental prognostic value with respect to both CE and all-cause death.

CONCLUSIONS Vasodilator stress Rb-82 PET-MPI provides incremental prognostic value to historical/clinical variables and rest LVEF to predict survival free of CE and all-cause death. An increasing percentage of ischemia on PET-MPI is associated with an increase in the risk of CE and all-cause death. Left ventricular ejection fraction reserve provides significant independent and incremental value to Rb-82 MPI for predicting the risk of future adverse events. (J Am Coll Cardiol Img 2009;2:846–54)

From the *Division of Nuclear Medicine and Molecular Imaging, Department of Radiology, and the †Noninvasive Cardiovascular Imaging Program, Departments of Medicine (Cardiology) and Radiology, Brigham and Women's Hospital, Boston, Massachusetts; and from ‡Los Angeles, California. Dr. Dorbala is a member of the Speakers' Bureau for Astellas and has received speaking honoraria from Bracco Diagnostics. Dr. Hachamovitch is a member of the Speakers' Bureau for Bracco Diagnostics and has received research grants from GE Healthcare. Dr. Di Carli has received research grants from GE Healthcare, Bracco Diagnostics, Siemens, and Astellas; is a member of the Speakers' Bureau for Bracco Diagnostics; and is a Consultant/Advisory Board member for Bracco Diagnostics.

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ercise, or dobutamine PET studies because of inherent differences in baseline patient risk and levels and duration of peak coronary flow achieved.

CONCLUSIONS

The percentage of ischemic myocardium on vasodilator stress Rb-82 PET-MPI is a powerful predictor of CE and survival in patients with known CAD or an intermediate to high pre-test likelihood of CAD. Rb-82 PET-MPI provides significant incremental value over the baseline clinical variables, rest LVEF and stress data. The addition of LVEF reserve provides significant independent and incremental value to Rb-82 MPI for stratifying risk of future serious adverse events.

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REFERENCES

1. Di Carli MF, Hachamovitch R. New technology for noninvasive evaluation of coronary artery disease. Circulation 2007;115:1464–80.
2. Sampson UK, Dorbala S, Limaye A, Kwong R, Di Carli MF. Diagnostic accuracy of rubidium-82 myocardial perfusion imaging with hybrid positron emission tomography/computed tomography in the detection of coronary artery disease. J Am Coll Cardiol 2007; 49:1052–8.
3. Dorbala S, Vangala D, Sampson U, Limaye A, Kwong R, Di Carli MF. Value of vasodilator left ventricular ejection fraction reserve in evaluating the magnitude of myocardium at risk and the extent of angiographic coronary artery disease: a 82Rb PET/CT study. J Nucl Med 2007;48:349–58.
4. Go RT, Marwick TH, MacIntyre WJ, et al. A prospective comparison of rubidium-82 PET and thallium-201 SPECT myocardial perfusion imaging utilizing a single dipyridamole stress in the diagnosis of coronary artery disease. J Nucl Med 1990;31:1899–905.
5. Stewart RE, Schwaiger M, Molina E, et al. Comparison of rubidium-82 positron emission tomography and thallium-201 SPECT imaging for detection of coronary artery disease. Am J Cardiol 1991;67:1303–10.
6. Bateman TM, Heller GV, McGhie AI, et al. Diagnostic accuracy of rest/stress ECG-gated Rb-82 myocardial perfusion PET: comparison with ECG-gated Tc-99m sestamibi SPECT. J Nucl Cardiol 2006;13:24–33.
7. Merhige ME, Breen WJ, Shelton V, Houston T, D'Arcy BJ, Perna AF. Impact of myocardial perfusion imaging with PET and (82)Rb on downstream invasive procedure utilization, costs, and outcomes in coronary disease management. J Nucl Med 2007; 48:1069–76.
8. Yoshinaga K, Chow BJ, Williams K, et al. What is the prognostic value of myocardial perfusion imaging using rubidium-82 positron emission tomography? J Am Coll Cardiol 2006; 48:1029–39.
9. Marwick TH, Shan K, Patel S, Go RT, Lauer MS. Incremental value of rubidium-82 positron emission tomography for prognostic assessment of known or suspected coronary artery disease. Am J Cardiol 1997;80: 865–70.
10. Sdringola S, Loghin C, Boccalandro F, Gould KL. Mechanisms of progression and regression of coronary artery disease by PET related to treatment intensity and clinical events at long-term follow-up. J Nucl Med 2006;47:59–67.
11. Hachamovitch R, Hayes SW, Friedman JD, Cohen I, Berman DS. Comparison of the short-term survival benefit associated with revascularization compared with medical therapy in patients with no prior coronary artery disease undergoing stress myocardial perfusion single photon emission computed tomography. Circulation 2003;107:2900–7.
12. Cox DR. Regression models and life-tables (with discussion). J R Stat Soc Ser 1972:187–220.
13. Greenland S. Modeling and variable selection in epidemiologic analysis. Am J Public Health 1989;79:340–9.
14. Pryor DB, Shaw L, McCants CB, et al. Value of the history and physical in identifying patients at increased risk for coronary artery disease. Ann Intern Med 1993;118:81–90.
15. Hachamovitch R, Berman DS, Morise AP, Diamond GA. Statistical, epidemiological and fiscal issues in the evaluation of patients with coronary artery disease. Q J Nucl Med 1996;40: 35–46.
16. Di Carli MF, Dorbala S, Meserve J, El Fakhri G, Sitek A, Moore SC. Clinical myocardial perfusion PET/CT. J Nucl Med 2007;48:783–93.
17. Schwaiger M, Ziegler S, Nekolla SG. PET/CT: challenge for nuclear cardiology. J Nucl Med 2005;46:1664–78.
18. Hachamovitch R, Rozanski A, Hayes SW, et al. Predicting therapeutic benefit from myocardial revascularization procedures: are measurements of both resting left ventricular ejection fraction and stress-induced myocardial ischemia necessary? J Nucl Cardiol 2006;13:768–78.
19. Lertsburapa K, Ahlberg AW, Bateman TM, et al. Independent and incremental prognostic value of left ventricular ejection fraction determined by stress gated rubidium 82 PET imaging in patients with known or suspected coronary artery disease. J Nucl Cardiol 2008;15:745–53.
20. Brown TL, Merrill J, Volokh L, Bengel FM. Determinants of the response of left ventricular ejection fraction to vasodilator stress in electrocardiographically gated (82)rubidium myocardial perfusion PET. Eur J Nucl Med Mol Imaging 2008;35:336–42.

Key Words: prognosis ■ imaging ■ tomography.

RT

image

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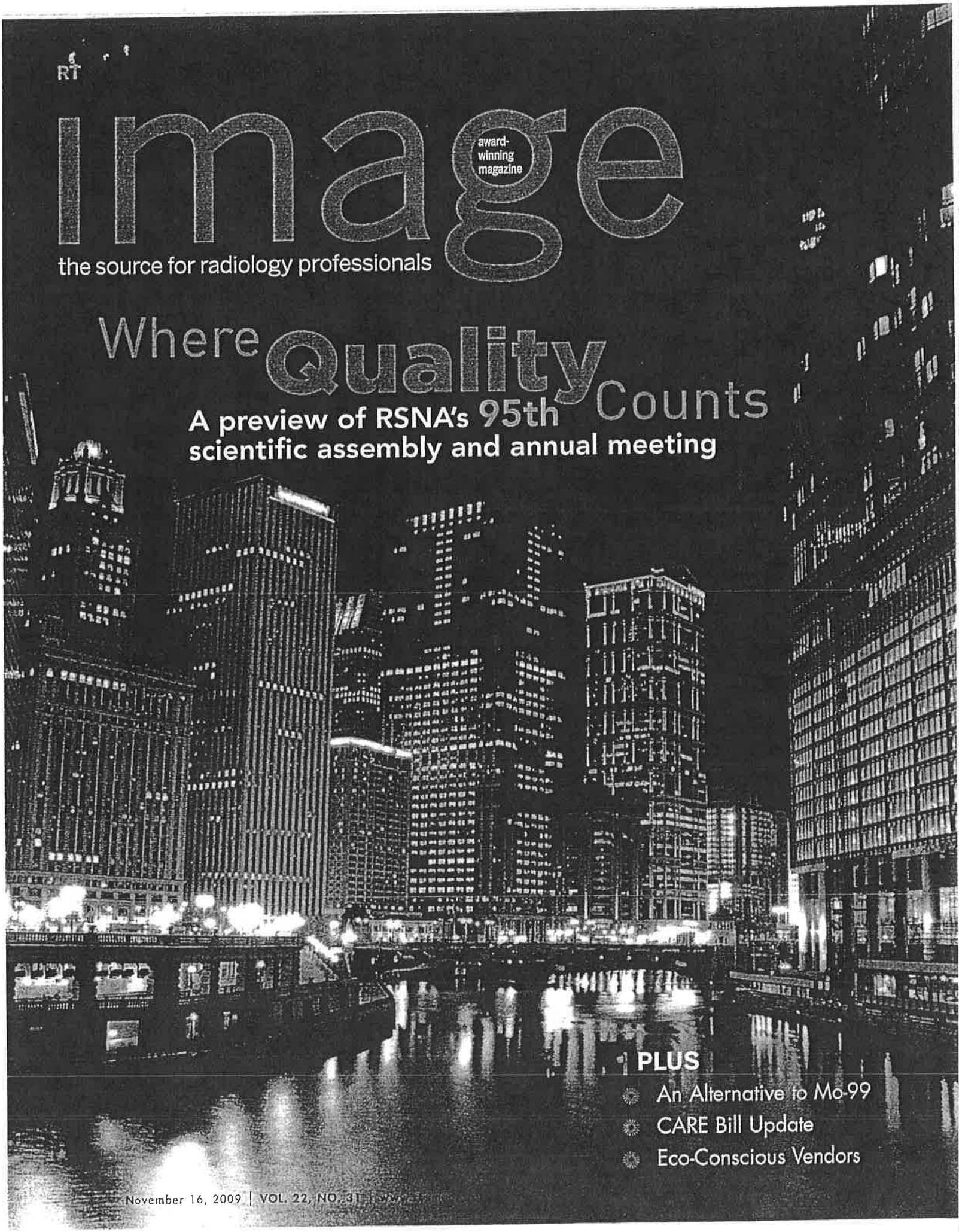
Where Quality Counts

A preview of RSNA's 95th scientific assembly and annual meeting



PLUS

- An Alternative to Mo-99
- CARE Bill Update
- Eco-Conscious Vendors

November 16, 2009 | VOL. 22, NO. 31

A Conversation with . . .

Kim Giordano, CNMT

Bracco's solution to the Mo-99 isotope crisis

MOLYBDENUM-99 (MO-99) IS THE PRECURSOR FOR TECHNETIUM-99M, *a radioisotope used in 80 percent of diagnostic and nuclear medicine procedures. However, earlier this year, following an unexpected shutdown at the Canadian nuclear reactor that provides 50 percent of the Mo-99 supply in the U.S., the nuclear medicine industry has been dealt a massive blow in the form of possible shortages.*

Only a handful of facilities around the world can generate quantities of Mo-99 that can be exported for commercial use – of those five reactors, three are in Europe, one is in Canada, and one is in South Africa. Since these medical isotopes cannot be stockpiled, disruptions at even one of those facilities can quickly affect the chain of supply to the entire industry, leaving today's healthcare professionals grasping for solutions.

One company – Princeton, N.J.-based Bracco Diagnostics Inc. – believes it has developed a viable solution to ease the strain of impending Mo-99 shortages with CardioGen-82, the only generator-based, cardiac PET perfusion imaging agent approved by the FDA. **rt image** *sits down with Kim Giordano, Bracco's vice president of corporate accounts and nuclear medicine, as well as a certified nuclear medicine technologist, to discuss what relief this product is expected to bring to the Mo-99 shortage.*

Q rt image: How does PET Myocardial Perfusion Imaging (MPI) provide a long-term solution to the current Mo-99 crisis?

A Kim Giordano: Since CardioGen-82® (Rubidium Rb-82 Generator) is not reliant upon the supply of Mo-99, it has much greater availability for use in performing nuclear cardiology studies. Many centers that are experiencing difficulty obtaining the isotopes used for MPI with SPECT also have access to a PET scanner. Using PET instead of SPECT for MPI has many clinical and logistical advantages. Now cardiac PET with CardioGen-82 offers even more benefits because patient studies no longer have to be postponed or canceled due to the Mo-99 shortage. Facilities that offer PET MPI as part of their cardiac imaging service can continue to maintain and expand their nuclear cardiology patient volumes.

Q image: What advantages does PET offer over SPECT, clinically and logistically, for CAD patients and interpreting physicians?

A Giordano: PET images provide more than twice as many photon counts as SPECT images. This, combined with improved spatial resolution and attenuation correction on all scans, enhances the overall image quality and diagnostic accuracy. CardioGen-82 PET offers imagers greater interpretive certainty versus SPECT – 96 percent versus 82 percent respectively. Moreover, typical PET MPI protocols are completed (gated rest and stress) in 30 minutes to 45 minutes, instead of about three hours with SPECT. Therefore, PET provides both clinical and logistical advantages for CAD patients and interpreting physicians.

Q image: Are there any patients who would not benefit from a cardiac PET study, or are there contraindications to the test?

A Giordano: CardioGen-82 has no known contraindications. According to Medicare, PET is reimbursed for many of the

Single-photon emission computed tomography

From Wikipedia, the free encyclopedia

Single-photon emission computed tomography (SPECT, or less commonly, SPET) is a nuclear medicine tomographic[1] imaging technique using gamma rays. It is very similar to conventional nuclear medicine planar imaging using a gamma camera. However, it is able to provide true 3D information. This information is typically presented as cross-sectional slices through the patient, but can be freely reformatted or manipulated as required.

The basic technique requires delivery of a gamma-emitting radioisotope (called radionuclide) into the patient, normally through injection into the bloodstream. On occasion, the radioisotope is a simple soluble dissolved ion, such as a radioisotope of gallium(III), which happens to also have chemical properties that allow it to be concentrated in ways of medical interest for disease detection. However, most of the time in SPECT, a marker radioisotope, which is of interest only for its radioactive properties, has been attached to a specific ligand to create a radioligand, which is of interest for its chemical binding properties to certain types of tissues. This marriage allows the combination of ligand and radioisotope (the radiopharmaceutical) to be carried and bound to a place of interest in the body, which then (due to the gamma-emission of the isotope) allows the ligand concentration to be seen by a gamma-camera.

Single-photon emission computed tomography

Intervention

A SPECT slice of the distribution of technetium exametazime within a patient's brain.

ICD-9-CM	92.0 (http://icd9cm.chrisendres.com/index.php?srchtype=procs&srchtext=92.0&Submit=Search&action=search)-92.1 (http://icd9cm.chrisendres.com/index.php?srchtype=procs&srchtext=92.1&Submit=Search&action=search)
MeSH	D015899
OPS-301 code:	3-72 (http://ops.icd-code.de/ops/code/3-72.html)

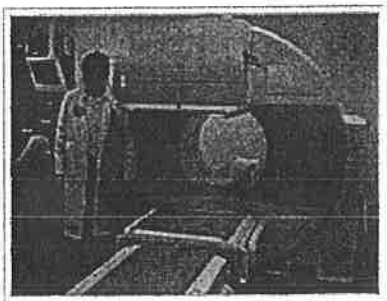
Contents

Principles

In the same way that a plain X-ray is a 2-dimensional (2-D) view of a 3-dimensional structure, the image obtained by a gamma camera is a 2-D view of 3-D distribution of a radionuclide.

SPECT imaging is performed by using a gamma camera to acquire multiple 2-D images (also called projections), from multiple angles. A computer is then used to apply a tomographic reconstruction algorithm to the multiple projections, yielding a 3-D dataset. This dataset may then be manipulated to show thin slices along any chosen axis of the body, similar to those obtained from other tomographic techniques, such as MRI, CT, and PET.

SPECT is similar to PET in its use of radioactive tracer material and detection of gamma rays. In contrast with PET, however, the tracer used in SPECT emits gamma radiation that is measured directly,

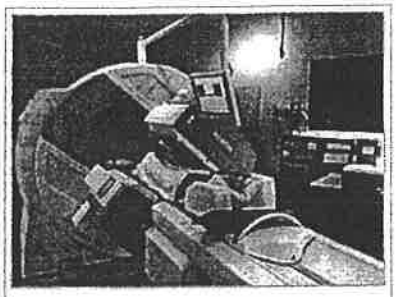


SPECT Siemens brand. It consists of

whereas PET tracer emits positrons that annihilate with electrons up to a few millimeters away, causing two gamma photons to be emitted in opposite directions. A PET scanner detects these emissions "coincident" in time, which provides more radiation event localization information and, thus, higher resolution images than SPECT (which has about 1 cm resolution). SPECT scans, however, are significantly less expensive than PET scans, in part because they are able to use longer-lived more easily-obtained radioisotopes than PET.

two gamma cameras.

Because SPECT acquisition is very similar to planar gamma camera imaging, the same radiopharmaceuticals may be used. If a patient is examined in another type of nuclear medicine scan but the images are non-diagnostic, it may be possible to proceed straight to SPECT by moving the patient to a SPECT instrument, or even by simply reconfiguring the camera for SPECT image acquisition while the patient remains on the table.



SPECT machine performing a total body bone scan. The patient lies on a table that slides through the machine, while a pair of gamma cameras rotate around her.

To acquire SPECT images, the gamma camera is rotated around the patient. Projections are acquired at defined points during the rotation, typically every 3–6 degrees. In most cases, a full 360-degree rotation is used to obtain an optimal reconstruction. The time taken to obtain each projection is also variable, but 15–20 seconds is typical. This gives a total scan time of 15–20 minutes.

Multi-headed gamma cameras can provide accelerated acquisition. For example, a dual-headed camera can be used with heads spaced 180 degrees apart, allowing 2 projections to be acquired simultaneously, with each head requiring 180 degrees of rotation. Triple-head cameras with 120-degree spacing are also used.

Cardiac gated acquisitions are possible with SPECT, just as with planar imaging techniques such as MUGA. Triggered by Electrocardiogram (EKG) to obtain differential information about the heart in various parts of its cycle, gated myocardial SPECT can be used to obtain quantitative information about myocardial perfusion, thickness, and contractility of the myocardium during various parts of the cardiac cycle, and also to allow calculation of left ventricular ejection fraction, stroke volume, and cardiac output.

Application

SPECT can be used to complement any gamma imaging study, where a true 3D representation can be helpful, e.g., tumor imaging, infection (leukocyte) imaging, thyroid imaging or bone scintigraphy.

Because SPECT permits accurate localisation in 3D space, it can be used to provide information about localised function in internal organs, such as functional cardiac or brain imaging.

Myocardial perfusion imaging

Main article: Myocardial perfusion imaging

Myocardial perfusion imaging (MPI) is a form of functional cardiac imaging, used for the diagnosis of ischemic heart disease. The underlying principle is that under conditions of stress, diseased myocardium receives less blood flow than normal myocardium. MPI is one of several types of cardiac stress test.

A cardiac specific radiopharmaceutical is administered, e.g., ^{99m}Tc-tetrofosmin (Myoview, GE healthcare), ^{99m}Tc-sestamibi (Cardiolite, Bristol-Myers Squibb). Following this, the heart rate is raised to induce myocardial stress, either by exercise or pharmacologically with adenosine, dobutamine, or dipyridamole (aminophylline can be used to reverse the effects of dipyridamole).

SPECT imaging performed after stress reveals the distribution of the radiopharmaceutical, and therefore the relative blood flow to the different regions of the myocardium. Diagnosis is made by comparing stress images to a further set of images obtained at rest. As the radionuclide redistributes slowly, it is not usually possible to perform both sets of images on the same day, hence a second attendance is required 1–7 days later (although, with a Tl-201 myocardial perfusion study with dipyridamole, rest images can be acquired as little as two hours post-stress). However, if stress imaging is normal, it is unnecessary to perform rest imaging, as it too will be normal; thus, stress imaging is normally performed first.

MPI has been demonstrated to have an overall accuracy of about 83% (sensitivity: 85%; specificity: 72%),[2] and is comparable with (or better than) other non-invasive tests for ischemic heart disease.

Functional brain imaging

Main article: Neuroimaging

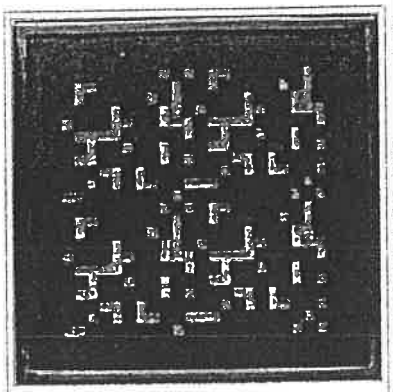
Usually, the gamma-emitting tracer used in functional brain imaging is ^{99m}Tc-HMPAO (hexamethylpropylene amine oxime). ^{99m}Tc is a metastable nuclear isomer that emits gamma rays that can be detected by a gamma camera. Attaching it to HMPAO allows ^{99m}Tc to be taken up by brain tissue in a manner proportional to brain blood flow, in turn allowing cerebral blood flow to be assessed with the nuclear gamma camera.

Because blood flow in the brain is tightly coupled to local brain metabolism and energy use, the ^{99m}Tc-HMPAO tracer (as well as the similar ^{99m}Tc-EC tracer) is used to assess brain metabolism regionally, in an attempt to diagnose and differentiate the different causal pathologies of dementia. Meta-analysis of many reported studies suggests that SPECT with this tracer is about 74% sensitive at diagnosing Alzheimer's disease vs. 81% sensitivity for clinical exam (cognitive testing, etc.). More recent studies have shown the accuracy of SPECT in Alzheimer's diagnosis may be as high as 88%.[3] In meta analysis, SPECT was superior to clinical exam and clinical criteria (91% vs. 70%) in being able to differentiate Alzheimer's disease from vascular dementias.[4] This latter ability relates to SPECT's imaging of local metabolism of the brain, in which the patchy loss of cortical metabolism seen in multiple strokes differs clearly from the more even or "smooth" loss of non-occipital cortical brain function typical of Alzheimer's disease.

^{99m}Tc-HMPAO SPECT scanning competes with fludeoxyglucose (FDG) PET scanning of the brain, which works to assess regional brain glucose metabolism, to provide very similar information about local brain damage from many processes. SPECT is more widely available, because the radioisotope used is longer-lasting and far less expensive in SPECT, and the gamma scanning equipment is less expensive as well. While ^{99m}Tc is extracted from relatively simple technetium-99m generators, which are delivered to hospitals and scanning centers weekly to supply fresh radioisotope, FDG PET relies on FDG, which is made in an expensive medical cyclotron and "hot-lab" (automated chemistry lab for radiopharmaceutical manufacture), and then delivered immediately to scanning sites because of the natural short 110-minute half-life of Fluorine-18.

Reconstruction

Reconstructed images typically have resolutions of 64×64 or 128×128 pixels, with the pixel sizes ranging from 3–6 mm. The number of projections acquired is chosen to be approximately equal to the width of the resulting images. In general, the resulting reconstructed images will be of lower resolution, have increased noise than planar images, and be susceptible to artifacts.


Coded aperture mask for gamma camera

Scanning is time consuming, and it is essential that there is no patient movement during the scan time. Movement can cause significant degradation of the reconstructed images, although movement compensation reconstruction techniques can help with this. A highly uneven distribution of radiopharmaceutical also has the potential to cause artifacts. A very intense area of activity (e.g., the bladder) can cause extensive streaking of the images and obscure neighboring areas of activity. (This is a limitation of the filtered back projection reconstruction algorithm. Iterative reconstruction is an alternative algorithm that is growing in importance, as it is less sensitive to artifacts and can also correct for attenuation and depth dependent blurring).

Attenuation of the gamma rays within the patient can lead to significant underestimation of activity in deep tissues, compared to superficial tissues. Approximate correction is possible, based on relative position of the activity. However, optimal correction is obtained with measured attenuation values. Modern SPECT equipment is available with an integrated X-ray CT scanner. As X-ray CT images are an attenuation map of the tissues, this data can be incorporated into the SPECT reconstruction to correct for attenuation. It also provides a precisely registered CT image, which can provide additional anatomical information.

Typical SPECT acquisition protocols

Study	Radioisotope	Emission energy (keV)	Half-life	Radiopharmaceutical	Activity (MBq)	Rotation (degrees)	Projections	Image resolution	Time per projection (s)
	technetium-		6	Phosphonates /					

Bone scan	99m	140	hours	Bisphosphonates	800	360	120	128 x 128	30
Myocardial perfusion scan	technetium-99m	140	6 hours	tetrofosmin; Sestamibi	700	180	60	64 x 64	25
Sestamibi parathyroid scan	technetium-99m	140	6 hours	Sestamibi					
Brain scan	technetium-99m	140	6 hours	HMPAO; ECD	555-1110	360	64	128 x 128	30
Neuroendocrine or neurological tumor scan	iodine-123 or iodine-131	159	13 hours or 8 days	MIBG	400	360	60	64 x 64	30
White cell scan	indium-111 & technetium-99m	171 & 245	67 hours	*in vitro* labelled leucocytes	18	360	60	64 x 64	30

SPECT/CT

In some cases a SPECT gamma scanner may be built to operate with a conventional CT scanner, with coregistration of images. As in PET/CT, this allows location of tumors or tissues which may be seen on SPECT scintigraphy, but are difficult to precisely locate with regard to other anatomical structures. Such scans are most useful for tissues outside the brain, where location of tissues may be far more variable. For example, SPECT/CT may be used in sestamibi parathyroid scan applications, where the technique is useful in locating ectopic parahyroid ademomas which may not be in their usual locations in the thyroid gland.[5]

See also

- Gamma camera
- Neuroimaging
- Functional neuroimaging
- Magnetic resonance imaging
- Positron emission tomography
- ISAS (Ictal-Interictal SPECT Analysis by SPM)

References

1. ^ SPECT (http://www.nlm.nih.gov/cgi/mesh/2011/MB_cgi?mode=&term=SPECT) at the US National Library of Medicine Medical Subject Headings (MeSH)
2. ^ Elhendy, A; Bax, JJ; Poldermans, D (2002). "Dobutamine stress myocardial perfusion imaging in coronary artery disease.". *Journal of Nuclear Medicine* **43** (12): 1634–46. PMID 12468513 (//www.ncbi.nlm.nih.gov/pubmed/12468513).
3. ^ Bonte FJ, Harris TS, Hynan LS, Bigio EH, White CL (2006). "Tc-99m HMPAO SPECT in the differential diagnosis of the dementias with histopathologic confirmation". *Clin Nucl Med* **31** (7): 376–8. doi:10.1097/01.rlu.0000222736.81365.63 (http://dx.doi.org/10.1097%2F01.rlu.0000222736.81365.63). PMID 16785801 (//www.ncbi.nlm.nih.gov/pubmed/16785801).
4. ^ Dougall NJ, Bruggink S, Ebmeier KP (2004). "Systematic review of the diagnostic accuracy of 99mTc-HMPAO-SPECT in dementia". *Am J Geriatr Psychiatry* **12** (6): 554–70. doi:10.1176/appi.ajgp.12.6.554 (http://dx.doi.org/10.1176%2Fappi.ajgp.12.6.554). PMID 15545324 (//www.ncbi.nlm.nih.gov/pubmed/15545324).
5. ^ [1] (http://www.ncbi.nlm.nih.gov/pubmed/18997051) PET/CT sestamibi vs. other modalities for parathyroid imaging

Further reading

- Herman, Gabor T. (2009). *Fundamentals of Computerized Tomography: Image Reconstruction from Projections* (2nd ed.). Springer. ISBN 978-1-85233-617-2..
- Elhendy *et al.*, Dobutamine Stress Myocardial Perfusion Imaging in Coronary Artery Disease, J Nucl Med 2002 43: 1634–1646 (http://jnm.snmjournals.org/cgi/content/abstract/43/12/1634)

SUPPORT LETTERS

NOTIFICATION OF INTENT
TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. Sections 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Karing Hearts Cardiology, PLLC (a private professional medical practice), owned and managed by Jeffrey Schoondyke, M.D. (a physician), intends to file an application for a Certificate of Need to initiate Cardiac PET services and to acquire Cardiac PET equipment, at its practice office at 701 State of Franklin Road, Suite 2, Johnson City, TN 37604, at a capital cost estimated at $500,000.

The project will not add or discontinue any other significant health service at this medical practice; and the project does not include any other type of major medical equipment.

The anticipated date of filing the application is on or before November 15, 2013. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

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318 Cumberland Street
Kingsport 423-392-0726
TFL-3823

Stewarts Hill Auction
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Applications will be accepted Monday through Friday from 8 am to 5 pm. The Johnson City Press is located at 204 W. Main St., Johnson City, or email your resume to snewcom@johnsoncitypress.com No phone calls for this position are accepted.

The Johnson City Press is currently accepting applications for **part-time telemarketing sales clerk.** We have openings in our morning, afternoon and evenings shifts. Must have a pleasant phone voice. This is a contracted position. Pay is performance based. Successful applicants must be able to begin immediately.

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STATE OF TENNESSEE

COUNTY OF DAVIDSON

JOHN WELLBORN, being first duly sworn, says that he is the lawful agent of the applicant named in this application, that this project will be completed in accordance with the application to the best of the agent's knowledge, that the agent has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete to the best of the agent's knowledge.

John L Wellborn
SIGNATURE/TITLE

Sworn to and subscribed before me this 15th day of November (Month), 2013 (Year) a Notary

Public in and for the County/State of Davidson.

KATHY M. NICHOLSON STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY, TENN.

Kathy M. Nicholson
NOTARY PUBLIC

My commission expires 3/8 (Month/Day), 16 (Year).

COPY-
SUPPLEMENTAL-1

Karing Hearts Cardiology, PLLC

CN1311-046

DSG Development Support Group

November 25, 2013

Phillip M. Earhart, Health Planner III
Tennessee Health Services and Development Agency
161 Rosa L. Parks Boulevard
Nashville, Tennessee 37203

RE: CON Application #1311-046
Karing Hearts Cardiology, PLLC

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. **Section A, Applicant Profile, Item 1**
   Please clarify the correct address of the applicant. The applicant states the address is 701 State of Franklin Road, but portions of the previously approved application, Molecular Imaging Alliance, CN1304-004 and the Architect's letter in this application, refer to the address as "North State of Franklin Road". Please clarify.

They are interchangeable for practical purposes. There is only one State of Franklin Road in Johnson City, and only one "701" State of Franklin Road address. That road changes direction as it crosses US Highway 321 (Market Street) west of downtown. It is called "North" on the north side of US 321, "West" on the south side of US 321 until it reaches I-26, and "East" as it proceeds west past I-26. Karing Hearts Cardiology is in the only building on State of Franklin Road with a "701" address; this can be verified by phoning Trinity Taxi Company in Johnson City, telephone 423-232-88911. Karing Hearts' building is locally referred to simply as "the 701 Building"; and it receives mail addressed to "State of Franklin Road" as well as to "North State of Franklin Road."

All the notifications of intent published and submitted in prior approved CN1304-004, and in this current application CN1311-046, omitted the word "North" from the project address. Service area residents know the location of the project. Persons who Google the 701 number with any of the three alternative street names will be directed to Karing Hearts Cardiology. The local postal delivery service delivers Karing Hearts' mail whether addressed to 701, 701 North, 701 West, or 701 East, State of Franklin Road.

Attached following this page is corrected page 5R to bring the Executive Summary into conformity with the notifications of intent in both applications.

4219 Hillsboro Road, Suite 203
Nashville, TN 37215
jwdsg@comcast.net
Tel 615.665.2022
Fax 615.665.2042

2. **Section A, Applicant Profile, Item 3**
   Please clarify if Karing Hearts Cardiology, PLLC is 100% owned by Dr. Jeffrey Schoondyke, MD. If not, please list the owners and percentage of ownership.

   It is wholly owned by Jeffrey Schoondyke, MD. As stated on page 7 of the application, he is the sole member (i.e., owner) of the PLLC. There are no current plans for his employed colleague, Dr. Davidson, to become an owner.

3. **Section B, Project Description, Item I**
   The applicant has requested consent calendar for this project. Please address the reason consent calendar is being requested as it relates to each of the following: 1) Need, 2) Economic Feasibility, and the 3) Orderly Development to Health Care.

   Need: The project is needed to assure patient access to a cardiac PET imaging service that is clinically important, and which has been available to this area for years. The service was recently granted CON approval to relocate to this site, under an owner who now does not wish to go forward with owning the service, if the cardiology practice which is its principal user is able to use the equipment as a practice-based modality.

   Economic Feasibility: The service currently operates with a positive margin, as an Outpatient Diagnostic Cener. It is reliably projected to continue to operate feasibly at the new location, as a practice-based modality. Continuing increases in utilization at the new location are probable, based on this practice's recent addition of an established cardiologist, and on the cardiac PET ODC's utilization increases since opening five years ago. Increased utilization will strengthen its economic feasibility. Project financing is available.

   Orderly Development: The project replaces a CON granted less than a year ago, for this same equipment, at this same location, to be utilized primarily by the same referring cardiology practice. The project is unopposed.

It is noted the applicant states the ODC owner (approved in CN1304-014) is seeking to exit the ODC business and to terminate its lease of the PET unit it now operates, without implementing the ODC at the new location in Johnson City. However, please clarify the following:

General Response: An overall description of the relationship of parties to this project may be helpful, in addition to the specific responses below.

A cardiac PET service was originally granted CN00701-010, in the form of an ODC in the town of Gray, in Washington County, in 2007. The ODC, Lifescan of Tennessee, LLC, was wholly owned by Soteria Imaging, a national imaging company.

In 2012, Soteria decided to exit this service and dispose of its holdings. Its largest referral source for cardiac PET at that time was Karing Hearts Cardiology (Dr. Jeffrey Schoondyke) in Johnson City. Karing Hearts' Vice President, Robert Gregory, agreed to purchase 100% of the ODC; and Dr. Schoondyke organized a group to purchase Soteria's 60% controlling interest in the leasing company that Soteria set up to own and lease PET equipment to its ODC. Today, Robert Gregory is still the sole owner of the ODC that offers the service at the Molecular Imaging ODC; and the same four individuals listed elsewhere in these responses are still the only owners of the equipment leasing company.

In 2013, it became apparent that only one cardiac PET unit was needed in Washington County, so the equipment leasing company arranged to sell the second PET unit to Wellmont Cardiology, which was awarded a CON to acquire that unit and move it to its practice office in Kingsport, in Sullivan County.

Mr. Gregory simultaneously received CON approval (C1304-004) to relocate his ODC with the one remaining cardiac PET unit to leased space adjoining Karing Hearts Cardiology in Johnson City. However, upon more closely identifying the capital costs of creating and maintaining a licensed ODC there, Mr. Gregory would prefer to let the medical practice take over the equipment lease and make cardiac PET simply a service of the practice. It would be less expensive to develop and to operate. Hence this current CON application.

a. The PET equipment lease agreement is between Karing Hearts Cardiology, PLLC and Lifescan Leasing, LLC. Lifescan Leasing, LLC has four members: please list those members.

In 2010, Soteria Imaging, the owner of Lifescan Tennessee, LLC dba Molecular Imaging Associates), formed an equipment leasing company to own and lease the PET units being used at Gray. That entity was Lifescan Leasing of Tennessee, LLC. It is not a party to this CON application. However, the following information is offered:

1. In December 2012, Soteria decided to sell its interest in the ODC and the leasing company. At that time, Lifescan Leasing was owned 60% by Soteria Imaging, and 40% by a separate LLC named "Positron Emission Technology Group, LLC" (or "PET-G"). PET-G was owned in 25% equal shares by Rob Gregory, Dr. Jeffrey Schoondyke, Dr. Bruce Boggs, and Julie Bentley, NP.

2. In December 2012, the four owners of PET-G purchased Soteria's 60% controlling interest in the leasing company, dividing *that 60% share* as follows: Dr. Boggs, Dr. Schoondyke, and Ms. Bentley acquired approximately 27.8% (rounded) and Robert Gregory acquired 16.7% (rounded). At the same time, Robert Gregory acquired ownership of the ODC itself. During 2013, the PET-G entity was dissolved and the same four owners acquired membership interests in the leasing company of approximately 28% each, except for Robert Gregory, who acquired approximately16%.

3. In summary, today the ownership interests of the ODC and the equipment leasing company are as follows:

Lifescan Tennesee, LLC (the ODC): 100% of the membership interests are owned by Robert Gregory.

Lifescan Leasing of Tennessee, LLC (the equipment leasing company that owns the PET equipment and leases it to the ODC):

Owner	Ownership Interest (Rounded)
Julie Bentley, Nurse Practitioner	28%
Jeffrey Schoondyke, M.D. (Cardiologist)	28%
Bruce Boggs, M.D. (Primary Care)	28%
Robert Gregory (Practice VP and Mgr)	16%
	100%

b. According to the State of Tennessee, Secretary of State, the principal and registered agent address of Lifescan Leasing LLC appears to be the same address as the prior approved CON application, Lifescan Tennessee, LLC dba Molecular Imaging Alliance, CN1304-014A. Please clarify.

LifeScan Leasing of Tennessee, LLC exists only to lease cardiac PET equipment to Lifescan Tennessee, LLC dba Molecular Imaging ODC. Mr. Gregory manages the business affairs of both entities. It is convenient for all correspondence to come to the same address.

c. Please provide documentation from the State of Tennessee, Secretary of State that Lifescan Leasing of Tennessee, LLC is an active entity.

It is active. Attached following this page is the documentation.

d. The web-site for Karing Hearts Cardiology located at http://karingheartscardiology.com/staff.php shows Rob Gregory as the Vice-President of Karing Hearts Cardiology, located at 701 N. State of Franklin Road, Suite2, Johnson City, TN. Please clarify if this is the owner of the previously approved CON application, Lifescan Tennessee, LLC dba Molecular Imaging Alliance, CN1304-014A.

Yes; Mr. Gregory is Vice President of Karing Hearts (he manages the practice), and he also owns 100% of the membership interests of LifeScan Tennessee, LLC dba Molecular Imaging Alliance, which holds CN1304-014A to move as a cardiac PET ODC from Gray to Johnson City.

e. Please clarify if Robert Gregory has any ownership interest in Lifescan Leasing, LLC or Karing Hearts Cardiology, PLLC.

Mr. Gregory owns no part of the PLLC. The PLLC, as stated in the application, has only one member (owner), who is Dr. Jeffrey Schoondyke. Mr.Gregory owns the interests in Lifescan Leasing, LLC that are shown in the above response to question 3a. His interests are minority interests.

f. The PET equipment appears to be owned by Karing Hearts Cardiology, PLLC (owned by Dr. Jeffrey Schoondyke) and leased to Lifescan Leasing, LLC (which Dr. Jeffrey Schoondyke is a member). Please clarify if there are any legal implications of possibly owning and referring patients to the PET equipment as being the lessee and owner.

SUPPLEMENTAL- # 1
November 26, 2013
12:40pm

No, Dr. Schoondyke does not own the PET equipment. It is owned by LifeScan Leasing of Tennessee, LLC, in which Dr. Schoondyke owns a minority membership interest, along with three other minority owners who are not related persons.

Dr. Schoondyke was advised by legal counsel that these relationships raise no issues of self-referral. He is a minority owner of a leasing company that receives a flat (unchanging) lease payment that does not vary either with (a) the referrals from Dr. Schoondyke's medical practice, or with (b) the total utilization of the leased equipment. The proposed equipment lease attached in the current application also specifies a flat lease rate that does not vary with any physician's referral volume and does not vary with the utilization of the equipment.

g. Please clarify if Lifescan Leasing of Tennessee, LLC has always maintained ownership of the proposed PET unit since it was in service at Molecular Imaging Alliance located in Gray, TN.

Soteria formed LifeScan Leasing of Tennessee, LLC on December 23, 2010. Before then, the PET equipment at Gray was owned by Soteria or by some Soteria subsidiary, such as Lifescan of Tennessee (the ODC)--the applicant does not know which.

h. Please clarify if Dr. Jeffrey Schoondyke has ownership in LifeScan Tennessee, LLC.

No; he does not have, and has never had, any ownership in Lifescan Tennessee, LLC.

i. It is noted Precision Nuclear, LLC will provide the applicant with radiopharmaceuticals. However, please clarify the address of Precision Nuclear, LLC. Please clarify if Dr. Jeffrey Schoondyke or Robert Gregory are members of the LLC or has ownership interests.

Precision Nuclear, LLC is located at 830 Suncrest Drive, Gray, TN 37615. Neither Dr. Schoondyke nor Robert Gregory has any ownership/membership interest in Precision Nuclear, LLC.

j. Please clarify if Karing Hearts will maintain possession of Suite 1 on the ground floor of the "701" Building" at the 701 North State of Franklin Road, Johnson, City, TN. Please explain how Suite 1 will be utilized by the applicant.

Karing Hearts Cardiology leases Suites 1, 2, and 3 currently. They are all integrated into a single practice office. Suite 1, which once was to be leased to Molecular Imaging, no longer exists as a separate space. The area formerly known as Suite 1 has now been partially built out by the practice, for SPECT stress test imaging, which is a modality of nuclear medicine. It already contains a hot lab, patient prep room, etc. as shown on the floor plans in the application. That area also has unfinished space available for a cardiac PET room and control room. Karing Hearts uses "Suite 2" as the address for its entire 3-suite office, to distinguish the practice from Suites 4 et seq. that are leased to other tenants.

k. Why was it profitable to file this CON verses acquiring the existing approved CON (CN1304-014A).

The lease, renovation costs, and operating expenses for this diagnostic modality will be lower as a practice-based service, than if it were developed as a licensed Outpatient Diagnostic Center. Compared to the outstanding ODC CN1304-004, there will be less space attributable to the service (and no lease at all), lower renovation costs (only needed in part of former Suite 1), and lower operating expenses (no licensing fees; sharing space and staff with the practice).

4. Section B, Project Description, Item II.A.
The applicant states the medical practice will seek to maintain the accreditation by the Intersocietal Accreditation Commission (IAC). In terms of the IAC accreditation, please answer the following:
a. Please indicate the current accreditation period and when it will be renewed.

Lifescan Tennessee, LLC is currently accredited through August 31, 2015.

b. Please indicate the accreditation fee and if the fee was accounted on the Projected Data Chart.

For nuclear cardiology testing, IAC accreditation fees currently total $3,300. Those were not included in the Projected Data Chart for CY2015. Attached following this page are revised Pages 45R (PDC) and 46R (notes) reflecting that additional expense for CY2015, even though if the project is completed before CY2015, that will be a CY2014 expense (which will not be an annual expense).

c. What areas is the applicant certified in by the IAC?

Karing Hearts Cardiology is IAC certified in Echocardiography. A copy of its certification is attached after this page.

5. Section B, Item II. E.
What is the age of the PET scanner?

As stated on page 19 of the application, it was manufactured in 2002, and used by Soteria Imaging at another location until it was moved to the ODC in Gray. That would make it 11 years old.

6. Section C, Need, Item 1.a. (Service Specific Criteria (Specific Criteria, Positron Emission Tomography) Item 6.a.-6f

a. Please provide documentation that the proposed PET unit is FDA-certified for clinical use.

This letter is attached following the IAC document after this page.

b. The applicant refers to "attachments" for questions 6.a-6f. Please specify where the attachments are located in the application and submit a replacement page.

Please see revised pages 25R and 26 R, following this page. Also provided is a revised page 62R listing Attachment B.II.E.1 as the location for the FDA approval letter that will soon be submitted.

7. Section C, Need, Item 1.a. (Service Specific Criteria (Specific Criteria, Positron Emission Tomography) Item 8a.

The applicant refers the reader to "attachments" in the application that documents underserved areas in the primary service area. Please provide a narrative response specific to this application and proposed service area.

Attached is a revised page 27R adding that information.

CERTIFICATE OF ACCREDITATION

INTERSOCIETAL ACCREDITATION COMMISSION
ECHOCARDIOGRAPHY | ICAEL
hereby recognizes

KARING HEARTS CARDIOLOGY, PLLC
701 NORTH STATE OF FRANKLIN ROAD
SUITE 2
JOHNSON CITY, TENNESSEE

as an
ACCREDITED FACILITY
in the area(s) of
ADULT TRANSTHORACIC

ACCREDITED FACILITY · ECHOCARDIOGRAPHY · IAC INTERSOCIETAL ACCREDITATION COMMISSION

PRESIDENT, ECHOCARDIOGRAPHY | ICAEL

SECRETARY, ECHOCARDIOGRAPHY | ICAEL

through the date of NOVEMBER 30, 2015

SUPPLEMENTAL- # 1

8. **Section C, Need, Item 6**
Does the projected PET volume consider that instead of being an ODC open to all comers versus now being limited to two (2) cardiologists at Karing Hearts?

Yes, the projection and accompanying narrative specify that this is referral data projected for two (2) cardiologists, and does not include any referrals to the service from outside the practice.

9. **Section C. Economic Feasibility Item 1 (Project Cost Chart)**
The letter from the Architect is noted. However, the address of the applicant in the letter is noted as N. State of Franklin Road. Please clarify.

Please see the explanation for this in response to your supplemental question #1 at the beginning of this letter. Local persons often add "North" to State of Franklin to indicate that they are located on State of Franklin Road north of US 231/Market Street.

10. **Section C, Economic Feasibility, Item 4**
Please provide a Historical Data Chart for Karing Hearts.

The requested chart with a notes page, numbered as pages 44a-44b, are attached following this page.

11. **Section C, Economic Feasibility, Item 6B.**
Table Ten is noted. However, it appears the average gross and net revenue charges in 2012 for Molecular Imaging Alliance, Gray is identical. Please clarify.

The table is in error. Attached following this page is revised page 48R, with Molecular Imaging Alliance's reported CY2012 gross and net revenues per procedure corrected to $4791 and $1855, respectively. That year the ODC remained under the ownership of Soteria Imaging. Mr. Rob Gregory acquired the ODC at the end of CY2012.

SUPPLEMENTAL- # 1
November 26, 2013
12:40pm

12. **Section C, Economic Feasibility, Item 9.**
a. The TennCare/Medicaid Gross Revenue of $123,830 or 6% in Year One is noted. However, please clarify if that includes revenue from Virginia Medicaid.

The TennCare/Medicaid Gross Revenue of $123,830 does include revenue from Virginia Medicaid. Gross Revenue from patients who are covered by Virginia Medicaid represent less than 1% (0.15%) of the applicant's total Gross Revenue.

b. Please indicate the gross revenue the applicant expects from Virginia Medicaid patients.

Approximately $3,095 in CY2015
Approximately $3,232 in CY2016

13. **Articles**
The applicant has provided a 4-page Article titled "*Single-photo Emission Computed Tomography*" from Wikipedia. Please clarify if Wikipedia is a reliable source for information regarding medical equipment.

The referenced article is about SPECT imaging, which cardiac PET imaging is steadily replacing. It was provided to the HSDA in Molecular Imaging's approved application CN1304-014. The applicant is seeking to be consistent with the prior application. In the judgment of Karing Hearts Cardiology, all the articles provided can be helpful background material for the Board. Wikipedia often provides language that is easier for some persons to understand than the language used in peer-reviewed medical journals. Journal articles and a magazine article were also attached.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please FAX or telephone me so that we can respond in time to be deemed complete.

Respectfully,

John Wellborn

John Wellborn
Consultant

SUPPLEMENTAL- # 1
November 26, 2013
12:40pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY: KARING HEARTS CARDIOLOGY--CARDIAC PET SERVICE

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

John Wellborn
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 26 day of NOVEMBER, 2013, witness my hand at office in the County of DAVIDSON, State of Tennessee.

NOTARY PUBLIC

My commission expires 1-11, 2017.

TIFFANY B. POULOSE
NOTARY PUBLIC
STATE OF TENNESSEE
DAVIDSON COUNTY
MY COMMISSION EXPIRES 1-11-2017

HF-0043

Revised 7/02

Phillip M. Earhart

From: Phillips, Brant <BPhillips@bassberry.com>
Sent: Friday, February 07, 2014 2:44 PM
To: Phillip M. Earhart
Cc: Melanie Hill
Subject: Crestwyn Behavioral Health -- support letters
Attachments: WMHI Support Letter.PDF; QUINCO Support Letter.PDF; PCS Support Letter.PDF; MMHI Support Letter.PDF; AHS Support Letter.PDF; BMHCC Support Letter.PDF; Senator Kelsey Support Letter.PDF; Senator Tate Support Letter.PDF; Rep. Mark White Support Letter.PDF

Phillip:

Thanks again for our call today. I will follow-up with the additional information we discussed as soon as I am able. In the meanwhile, I wanted to forward to you the support letters that we have received thus far on this project. You may have one or two of these already, but I am sending again just in case not. In addition, we are told that State Rep. Curry Todd has sent a support letter to HSDA directly. Please let me know if you have not received it. Finally, we are expecting a few additional support letters. I will forward those to your as promptly as I can.

Many thanks. Have a good weekend.

Brant Phillips
615 742 7723 • 615 742 2842 F • 615 268 8049 C
bphillips@bassberry.com

From: Phillip M. Earhart [mailto:Phillip.M.Earhart@tn.gov]
Sent: Thursday, February 06, 2014 1:56 PM
To: Phillips, Brant
Subject: RE: Crestwyn Behavioral Health

Thank you.

From: Phillips, Brant [mailto:BPhillips@bassberry.com]
Sent: Thursday, February 06, 2014 1:53 PM
To: John Wellborn; Phillip M. Earhart
Subject: RE: Crestwyn Behavioral Health

Phillip:

John Wellborn shared your email with me. Thank you for your question. I will reach out to the client this afternoon to confirm that there is no confidentiality agreement / issue that would prevent us from sharing that information with you at this point. I do not believe there is, but I want to confirm. Once I have that confirmation, I will get back with you promptly. In the meanwhile, do not hesitate to contact me.

Many thanks.

Brant Phillips
615 742 7723 • 615 742 2842 F • 615 268 8049 C
bphillips@bassberry.com

------ Forwarded Message
From: "Phillip M. Earhart" <Phillip.M.Earhart@tn.gov>
Date: Thu, 6 Feb 2014 18:23:54 +0000
To: John Wellborn <jwdsg@comcast.net>
Subject: Crestwyn Behavioral Health

John

Good afternoon. If possible, please disclose the name of the hospital that will have 20% ownership in Crestwyn Behavioral Health. In the supplemental, it was noted the 20% owner would be communicated to HSDA staff prior to the HSDA Board's review of the Crestwyn application. Thanks.

Phillip Earhart
Health Services Development Examiner
Health Services & Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243
(615)-741-7819 (direct line)
(615) 741-2364 (front office)
(615) 741-9884 (fax)
www.state.tn.us\hsda <http://www.state.tn.us/hsda> *(website)*

------ End of Forwarded Message

Phillip M. Earhart

From: John Wellborn <jwdsg@comcast.net>
Sent: Thursday, February 06, 2014 1:43 PM
To: Phillip M. Earhart
Subject: Re: Crestwyn Behavioral Health

Phillip, I am forwarding this to Acadia's attorney, Brant Phillips, for a response.
Please call me if you need more information. Thanks--

On 2/6/14 12:23 PM, "Phillip M. Earhart" <Phillip.M.Earhart@tn.gov> wrote:

John

Good afternoon. If possible, please disclose the name of the hospital that will have 20% ownership in Crestwyn Behavioral Health. In the supplemental, it was noted the 20% owner would be communicated to HSDA staff prior to the HSDA Board's review of the Crestwyn application. Thanks.

Phillip Earhart
Health Services Development Examiner
Health Services & Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243
(615)-741-7819 (direct line)
(615) 741-2364 (front office)
(615) 741-9884 (fax)
www.state.tn.us\hsda <http://www.state.tn.us/hsda> *(website)*

John Wellborn
Development Support Group
4219 Hillsboro Road, Suite 210
Nashville, TN 37215
Office 615-665-2022
Mobile 615-438-6709
Fax 615-665-2042
email jwdsg@comcast.net

HSDA Contact Form

CON ProjectName/Number: _____

Person Contacted: _____

Phone Number or E-mail Address: _____

Contact Summary:

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Signature/Title/Date:

_____

HF-0058

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Johnson City Press, which is a newspaper of general circulation in Washington County, Tennessee, on or before November 10, 2013, for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. Sections 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that Karing Hearts Cardiology, PLLC (a private professional medical practice), owned and managed by Jeffrey Schoondyke, M.D. (a physician), intends to file an application for a Certificate of Need to initiate Cardiac PET services and to acquire Cardiac PET equipment, at its practice office at 701 State of Franklin Road, Suite 2, Johnson City, TN 37604, at a capital cost estimated at $500,000.

The project will not add or discontinue any other significant health service at this medical practice; and the project does not include any other type of major medical equipment.

The anticipated date of filing the application is on or before November 15, 2013. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

John L. Wellborn 11-8-13 jwdsg@comcast.net

(Signature) (Date) (E-mail Address)

CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
OFFICE OF HEALTH STATISTICS
615-741-1954

DATE: January 30, 2014

APPLICANT: Karing Hearts Cardiology Cardiac PET Service
701 State of Franklin Road, Suite 2
Johnson City, TN 37604

CON# 1311-046

CONTACT PERSON: John Wellborn
Development Support Group
4219 Hillsboro Road, Suite 210
Nashville, TN 37215
615-665-2022

COST: $391,585.00

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with Tennessee's State Health Plan, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:
The applicant, Karing Hearts Cardiology, PLLC, a cardiology practice operated in Johnson City, Tennessee and owned solely by Dr. Jeffrey Schoondyke, M.D., seeks Certificate of Need approval to initiate Cardiac PET services and to acquire Cardiac PET equipment at its practice office at 701 State of Franklin Road, Johnson City, Tennessee.

In July 2013, the HSDA board approved CON 1304-014 for the relocation of Molecular Imaging Alliance's existing cardiac PET ODC to be moved from Gray to Johnson City, Tennessee, into an office building occupied by Karing Hearts Cardiology. The current application being presented intends to replace CON 1304-014.

The owner of Molecular Imaging Alliance ODC, Dr. Robert Gregory, desires to exit the business and terminate the lease of the PET equipment without implementing the ODC at the Johnson City location. Karing Hearts Cardiology, which is the largest referral source to the ODC, seeks to lease the same PET unit currently being operated by the ODC. Karing Hearts Cardiology desires to offer Cardiac PET as a service to their practice rather than to acquire the ODC ownership. Once the current CON application is approved, previous CON 1304-014 will be turned in and voided.

The proposed service location is in a building owned by Dr. Schoondyke and his wife. The medical practice, Karing Hearts Cardiology, will house the PET service in 905 square feet of space it currently leases from the building owner. No new construction will be required, although heavy renovation will be necessary on 556 SF, at a cost of $110.50 SF.

The project cost is $391,585. The capital cost for moving the PET system and renovating the site will be $138,550, funded by a local bank as acknowledged in attachment to the application.

per month.

There have been two prior CON approvals for the same service, with the latest being in July 2013, for the relocation from Gray, Tennessee to Johnson City, Tennessee, to the same building and room as planned in CON C1304-004. The need for this project arises from the holder of CON C1304-004 decision to exit the ODC business and not implement the relocation of PET services, which would jeopardize the continued access for cardiac PET services in the area. The only other Cardiac PET unit in the area is located in Kingsport, Tennessee and not available to patients who are not in the practice of Wellmont Cardiology Services.

In July 2013, Wellmont Cardiology Services was granted CON approval to acquire one of two cardiac PET units that the ODC operated, and move it to Kingsport, Tennessee. At the same meeting, Molecular Imaging Associates ODC was approved to move its remaining unit from Gray to Johnson City, Tennessee.

TENNCARE/MEDICARE ACCESS:
The applicant participates in the Medicare and TennCare programs and has contractual agreements with BlueCare, TennCare Select, United Community Healthcare Plan, and Virginia Medicaid. The payor mix for the medical practice is 60% Medicare and 6% TennCare.

Table twelve, on page 51 of the application shows year one projected revenues of $1,238,299 at 60% of gross revenue for Medicare and $123,830 at 6% of gross revenue for TennCare. Indigent care is projected at 3% of gross revenue.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

Project Costs Chart: The projected Costs Chart is located in Section C(II) on page 41 of the application and states a total estimated cost of $391,585.

Historical Data Chart: On page 35 of the application, Table Seven shows the historic PET utilization for the ODC collected from the HSDA Equipment Registry. From 2009 to 2012, the ODC utilization increased more than 17%. The applicant reports the ODC performed 411 procedures in 2009, 342 procedures in 2010, 514 procedures in 2011, and 668 procedures in 2012. There appears to be an error in the applicant's number for 2012, as the applicant reports 668 procedures for 2012, but the HSDA data shows only 623 procedures. This error does not significantly change the projected growth rate.

**Note to Agency Members: The historical procedure volumes taken from the HSDA Equipment Registry for Molecular Imaging Alliance are the sum of procedures for two PET units being operated during the reporting periods.*

Projected Data Chart: The revised Projected Data Chart is located on page 45R of the additional Supplement #1. The applicant projects 678 procedures in year one and 745 procedures in year two with a net operating income of $48,868 and $40,049 each year, respectively.

The projected average gross charges are $3,044 and $2,893 for years 2015 and 2016, respectively. These numbers closely resemble the projected charges of the recently approved initiation of PET services for Wellmont Cardiology Services, and also the approved relocation of Molecular Imaging Alliance ODC.

The medical practice has just added a second cardiologist who brings an established patient base and is projected to add a 25% increase for PET referrals in 2014. An increase of 10% PET referrals from the medical practice is expected for years 2015 and 2016.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:
This project replaces CON 1304-041 that was granted for the same equipment, at the same location, to be utilized primarily by the same referring cardiology practice. The project does not add services, but merely changes ownership and location of existing services.

The approval to allow Karing Hearts to initiate Cardiac PET services will improve accessibility for both patients and the cardiologists. Karing Hearts is the largest referral to the ODC. The average distance from Johnson City to the current ODC location in Gray, Tennessee is 12 miles. By relocating the cardiac PET unit to the Karing Hearts office space, the physicians and their patients will no longer have to commute to another location. Approval of this project will ensure the continued accessibility to a needed technology leading to improved diagnosis and patient outcome.

Dr. Jeffrey Schoondyke is a member of the medical staff at Johnson City Medical Center, with which Karing Hearts Cardiology will have a transfer agreement if this project is approved.

The cardiac PET unit is currently accredited by the Intersocietal Accreditation Commission (IAC). The applicant states the medical practice will seek to maintain this accreditation if the project is approved.

Karing Hearts is not presently affiliated with institutions for the training of healthcare professionals.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in Tennessee's State Health Plan.

PET Standards and Criteria

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter.

   Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1,600 procedures per year if the unit is operated more than five (5) days per week.

   The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

   For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

   As a physician practice, the applicant is unlikely to ever meet the minimum standards. The applicant states criterion is not applicable as this project is not proposing a new PET unit, but rather a change of current ownership of existing equipment.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population.

Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

Criterion is not applicable as this project is not proposing a new PET unit, but rather a change of current ownership of existing equipment. However, approximately 85% of patients will come from the primary service area of Washington, Carter, and Unicoi Counties.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

The only other dedicated cardiac PET unit in the service area belongs to Wellmont Health Systems in Kingsport. This unit is not available to patients who are not in the practice of Wellmont Cardiology Services.

Molecular Imaging Alliance plans to discontinue the ODC business, thus no dedicated cardiac PET services will be available in the service area.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

The criterion is not applicable as it pertains to proposed new mobile PET.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures /day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The criterion is not applicable as the project does not add additional PET units to the service area, but rather a change of ownership of existing equipment.

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

The criterion is not applicable as the project does not add additional PET units to the service area, but rather a change of ownership of existing equipment.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.

a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

The FDA approval letter is included in the supplemental information.

b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.
A letter from the project architect declaring intent to follow all applicable codes and standards is included in Attachment C, Economic Feasibility-1.

c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

The applicant provides a copy their policy pertaining to emergencies.

d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

The applicant provides a copy of the medical necessity protocols.

e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

Dr. Schoondyke is a board certified cardiologist and has been medical director of for the cardiac PET services at the Gray ODC for several years. He is trained and experienced in the use and interpretation of cardiac PET studies. Karing Hearts Cardiology currently holds an active license for handling radioactive substances.

f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

Dr. Jeffrey Schoondyke is a member of the medical staff at Johnson City Medical Center, with which Karing Hearts Cardiology will have a transfer agreement if this project is approved.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

The applicant commits to comply with the requirement to submit the required data for the HSDA equipment registry.

8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

The applicant provides documentation from the Health Resources and Services Administration website of each Federally-designated "Medically Underserved Area" in the project's primary service area which includes Carter, Unicoi, and districts 5, 8 and 9 of Washington Counties.

b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

The applicant is not claiming this factor for special consideration at this time.

c. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

This application is not submitted by a safety net hospital, children's hospital or a hospital with a comprehensive cancer program.

d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

The applicant participates in the Medicare and TennCare programs and has contractual agreements with BlueCare, TennCare Select, United Community Healthcare Plan, and Virginia Medicaid. The payor mix for the medical practice is 60% Medicare and 6% TennCare.